

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and  
ANTHONY CUTONE,

Plaintiffs,

v.

ELI LILLY AND COMPANY,

Defendant.

CIVIL ACTION No. 04-CV-12725 (JLT)

AFFIDAVIT OF AARON M. LEVINE, ESQ.  
REGARDING AUTHENTICATION OF DOCUMENTS

I, Aaron M. Levine, declare under penalty of perjury that the following is true and correct:

1. Attached as Appendix 1 is a true copy of a select page from the National Cancer Institute, National Institute of Child Health and Human Development & National Institutes of Health Booklet, Were You Born Between 1938 and 1971 Or Pregnant Then? If So, You Could Be Exposed To DES (Jan. 1995).

2. Attached as Appendix 2 is a true copy of Lilly Research Laboratories et al, Withdrawal of Approval of 28 New Drug Applications (Food & Drug Admin., 65 Fed. Reg 55,164-55165) (Sept. 13, 2000).

3. Attached as Appendix 3 is a true copy of Robert K. Enders, Mink Production in Relation to Stilbestrol, in The Fur Journal, Sept.-Oct. 1950, at 4, 10.

4. Attached as Appendix 4 is a true copy of R.R. Greene, M.D., et al., Experimental Intersexuality: The Paradoxical Effects of Estrogens on the Sexual Development of the Female Rat, in The Anatomical Record 429 (Edward A. Boyden et al eds., 1939).

5. Attached as Appendix 5 is a true copy of selected pages from W.J. Dieckmann, M.D., et al., Does the Administration of Diethylstilbestrol During Pregnancy Have Therapeutic Value?, 66 Amer. J. of Ob. & Gyn. 1062 (Howard C. Taylor et al eds., 1953).

6. Attached as Appendix 6 is a true copy of selected pages of Defendant Eli Lilly and Company's Responses to Plaintiffs' First Set of Interrogatories and First Request for Production of Documents and/Or Tangible Things, dated August 15, 2005.

7. Attached as Appendix 7 is a true copy of the Affidavit of Harold B. Sparr, R.Ph., D. Ph., M.S., dated May 16, 2006.

8. Attached as Appendix 8 is a true photograph of the Bristol-Myers Squibb, 100mg DES pill with the "Squibb" imprint.

9. Attached as Appendix 9 is a true copy of the Affidavit of Julie Zhang, dated May 22, 2006, with a true photograph of a Diethylstilbestrol bottle and pill manufactured by Eli Lilly and Company.

10. Attached as Appendix 10 is a true photograph of the Diethylstilbestrol bottle and pills manufactured by Eli Lilly and Company.

11. Attached as Appendix 11 is a true copy of the Report of Harold B. Sparr, R. Ph., D Ph., M.S., dated October 12, 2004.

12. Attached as Appendix 12 is a true copy of the Amended Statement of Philip J. Cafferty, dated October 22, 2003.

13. Attached as Appendix 13 is a true copy of selected pages from the Deposition of Lorne Person in Berman v. Abbott Lab., No. 2244 (Pa. Ct. Com. Pl. 1993) and Nierenberg v. Abbott Lab., No. 2958 (Pa. Ct. Com. Pl. 1993), dated April 22, 1994.

14. Attached as Appendix 14 is a true copy of the Statement of Philip McGovern, M.D., dated September 9, 2004.

15. Attached as Appendix 15 is a true copy of Warehousing and Distribution Service Agreement, Eli Lilly and Company to Wholesalers (Jul. 1, 1970), which was attached as Exhibit A to Defendant Eli Lilly and Company's Response to Plaintiff's First Set of Interrogatories No. 2 (Aug. 15, 2005).

16. Attached as Appendix 16 is a true copy of selected pages from Color Additives, Hearing on H.R. 7624 and S. 2497 Before the House Comm. on Interstate and Foreign Commerce, 86th Cong. 265, 277, 283 (1960) (statement of Thomas Carney, Vice President, Eli Lilly & Co.).

17. Attached as Appendix 17 is a true copy of the Memorandum Opinion of Order denying Summary Judgment in Dunseth v. Eli Lilly & Co., No. 03-cv-02123 (D.D.C. Sept. 16, 2005).

18. Attached as Appendix 18 is a true copy of the Memorandum Opinion and Order Denying Motion for Summary Judgment in Gassman v. Eli Lilly, No. 03-02592 (D.D.C. Dec. 29, 2005).

19. Attached as Appendix 18 is a true copy of the Memorandum Opinion and Order Denying Motion for Summary Judgment in Clayton v. Eli Lilly, No. 04-1363 (D.D.C. Mar. 16, 2006).

20. Attached as Appendix 20 is a true copy of selected pages from the Deposition of Virginia Camporesi dated October 27, 2005.

21. Attached as Appendix 21 is a true copy of Physicians Desk Reference to Pharmaceutical Specialties and Biologicals, 224, 819-20 (Medical Economics, Inc., 23rd ed. 1969).

22. Attached as Appendix 22 is a true copy of the Report of Henneleore Vanderschmidt, Ph. D., dated April 13, 2004.

23. Attached as Appendix 23 is a true copy of the Minute Order Denying Motion for Summary Judgment in Kogen v. Eli Lilly, No., No. SACV 03-0962 (C.D. Cal., July 22, 2003).

24. Attached as Appendix 24 is a true copy of the Order Denying Summary Judgment in Woolfolk v. Eli Lilly & Co., No. C03-3577 (W.D. Wash., Mar. 15, 2005).

25. Attached as Appendix 25 is a true copy of the Minute Order Entry Denying Motion for Summary Judgment in Brooks v. Eli Lilly and Co. et al., No. 1:03-cv-1796 (D.D.C. July 28, 2005).

26. Attached as Appendix 26 is a true copy of the Statement of James P. DellaVolpe, dated April 22, 2004.

I declare under the penalty of perjury that the foregoing is true and correct.

/s/ Aaron M. Levine

Aaron M. Levine

Dated: May 25, 2006

21. Attached as Appendix 21 is a true copy of Physicians Desk Reference to Pharmaceutical Specialties and Biologicals, 224, 819-20 (Medical Economics, Inc., 23rd ed. 1969).

22. Attached as Appendix 22 is a true copy of the Report of Hannelore Vanderschmidt, Ph. D., dated April 13, 2004.

23. Attached as Appendix 23 is a true copy of the Minute Order Denying Motion for Summary Judgment in Kogen v. Eli Lilly, No., No. SACV 03-0962 (C.D. Cal., July 22, 2003).

24. Attached as Appendix 24 is a true copy of the Order Denying Summary Judgment in Woolfolk v. Eli Lilly & Co., No. C03-3577 (W.D. Wash., Mar. 15, 2005).

25. Attached as Appendix 25 is a true copy of the Minute Order Entry Denying Motion for Summary Judgment in Brooks v. Eli Lilly and Co. et al., No. 1:03-cv-1796 (D.D.C. July 28, 2005).

26. Attached as Appendix 26 is a true copy of the Statement of James P. DellaVolpe, dated April 22, 2004.

I declare under the penalty of perjury that the foregoing is true and correct.

/s/ Aaron M. Levine

Aaron M. Levine

Dated: May 25, 2006

**CERTIFICATE OF SERVICE**

I, Erica Tennyson, hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non registered participants on May 25, 2006.

s/ Erica Tennyson

Erica Tennyson (BBO# 660707)

# APPENDIX 1

**Were You Born Between  
1938 and 1971**

**Or Pregnant Then?**

**If So, You Could**

**Be Exposed To**

**DIES**

**National Cancer Institute**

**National Institute of Child Health and Human Development**

**National Institutes of Health**

# **APPENDIX 2**

Apr. 13 2001 12:53PM PL

Wysięczyński Unap://www.pharmcase.com/FederalRegister/041100FR/Lilly091



ACTION: Notice.

DATE: Effective September 30, 2000.

**SUPPLEMENTARY INFORMATION:** The holders of the applications listed in the table in this document have informed FDA that these drugs are no longer marketed and have requested that FDA withdraw approval of the applications. The applicants have also, by their request, waived their opportunity for a hearing.

((Page 5526511

Post-It® Fax Note	7071	Date	Y Cl pages	2
To	Assume	From	Pat Condy	
Co.	Pat	Co.		
Phone #		Phone #		
Fax #		Fax #		

Application No.	Drug
NDA 4-018	Diethylstilbestrol (DES) Injection.
NDA 4-019	DES Tablets.
NDA 4-040	DES Suppository.
NDA 4-041	DES Tablets.
NDA 4-056	Scilletin Tablets (Diethylstilbestrol Tablets US3).
NDA 6-127	Isuprel (Isoproterenol Hydrochloride) Inhalation Solution.
NDA 7-171	Megacortin Injection (Dimethyl Tubocurarine Chloride).
NDA 8-392	Hydrazid (Isoniazid US3) Tablets, Syrup, Capsules.
NDA 9-052	Reipar (Aminosalicylic Acid Resin Powder).

# **APPENDIX 3**

# The Fur Journal

VOLUME XVI

SEPTEMBER-OCTOBER • 1950

NUMBER 7

## Mink Production in Relation to Stilbestrol

By Robert K. Eaders, Agent, and William Lloyd Merrills, Agent, Bureau of Animal Industry and Swarthmore College cooperating.

The use of poultry waste in the feeding of mink has become widespread. Various sources estimate that between 40,000 and 50,000 of these animals have received this feed during the past year. Where the product contained some active estrogen its use appears to have resulted in breeding failures, some complete, some partial. Circumstantial evidence indicates that the substance involved is diethylstilbestrol. This synthetic estrogenic hormone was released for use in fattening poultry in the fall of 1947. It has come into wide use in the chemical "castration" of poultry and its use is being extended rapidly. It is not known whether all waste from "caponettes" which is a common name applied to treated birds, is harmful or whether only the pellets of the hormone that remain unabsorbed by the bird cause breeding failures in mink. Here again circumstantial evidence indicates that it is the residue of the unabsorbed pellet that gives the waste from treated birds its undesirable quality.

Experimental proof that diethylstilbestrol injected into or fed to female mink during the breeding season will bring about breeding but will interfere with the production of kits has been in existence for four years. Some of the evidence was published in 1947. In fact, this hormone is so potent that mink deprived of their ovaries will attempt mating, if they are given this hormone, during the breeding season. But diethylstilbestrol does not act like the natural estrogens of the mink, for while it induces breeding behavior it does not bring about vulvar swelling. Diethylstilbestrol, moreover, interferes with the follicles in which the eggs are growing, so in spite of breeding few if any kits will be born.

In 1948 and '49 we tried to get results from mink breeders who asked for this hormone to use on females still unbred at the end of the season. A number used the hormone but only a few were interested enough in the experiment to send in their results. Those cooperative enough to do so reported successful matings but no live kits, so one is led

to believe that the breeders who did not report were disappointed in reproduction, too. These cooperators were warned at the time the material was sent to them that its use was experimental, and that they were dealing with a very potent hormone. One must remember that these females were not treated until it was clear that they were not likely to breed and that production from late matings is poor under normal conditions. It is fair to assume, however, that part of the failure to produce kits arose from the effect of the diethylstilbestrol on the ovary.

### Total Failures

The following cases are presented to illustrate the type of troubles encountered and to show how an analysis of the known facts, even when they are not supported by experimental work, can point out dangers in feeding material suspected of containing a synthetic estrogen. Since the use of synthetic estrogens in fattening poultry is expected to increase threefold this year, the fur farmer who plans to feed the poultry waste should be alert to the dangers.

When chicken waste, suspected of containing "caponettes," was fed from November to March the mink so fed produced not a single kit. When fed from November to June the same disastrous results followed as for the shorter interval. No one knows how much diethylstilbestrol these animals received, nor does anyone know how much is required over such a length of time to bring about these failures. It is suspected that chicken waste with diethylstilbestrol was the factor involved, for cats fed the same feed bred continuously but did not produce kittens until the feed had been discontinued for some months. The ovaries of kit minks fed this diet showed, on sectioning and examination under the microscope, a considerable disturbance of normal development.

When chicken waste again suspected of containing "caponette" material that had had pellets of diethylstilbestrol implanted under the skin was fed for a long time but not at a high level, total failure of reproduction followed the feeding. Here again cast living on the same feed as the mink bred furiously

and continuously but did not produce kittens. This effect on cats is emphasized, for ovulation in these animals follows copulation much as in mink but unlike mink cats go out of heat following ovulation. Continuous heat without the production of kittens shows that some hormone, either the cat's own or that taken in the feed, kept these animals in heat and interfered with the physiological processes either of ovulation, fertilization or implantation but most probably ovulation. Had the cats ovulated and corpora lutea formed as under normal conditions, they would have gone out of heat for 36 days even though fertilization did not follow ovulation. We can infer that it was the failure of ovulation that was responsible in part for the continuous heat. This type of behavior of cats on ranches many miles apart but all feeding on poultry waste is indicative that in each case the chicken waste contained some ingredient that brought about this unnatural condition, for chicken waste was about the only ingredient common to the mix fed at all these ranches.

On another ranch, waste containing heads of both chickens and turkeys was used in the feed from January until March. Subsequent check of the source of supply verified the fact that some of the waste was from poultry treated with diethylstilbestrol. On this ranch the males would not copulate and on examination in early March the testes proved to be as small as they usually are in December. These animals were treated with iodized casein from March 15 to April 5. Since the males were not in breeding condition, three males were brought in from unaffected ranches. Forty per cent of the females bred but of these only 4.4% bore litters. All these litters were sired by one male so it is possible that the other two males were at fault. Even if these two males had been as good as the third male, only 13.2% of the females bred would have produced litters. Because only 40% of the females were bred and because only 4.4% of these bore litters, the percentage of females kept over bearing litters was less than 1%! Once again the reader must remember that these matings took place late in the season. An important finding

(Continued on Page 10)

## FUR FARMERS

Can have your Pelts made into Garments of choice in type and style to suit.

Also

Cleaned and Glazed. Remodel or Repair All Kinds of Furs.

### DEDERER'S FINE FURS

In the Fur District

615 National Bldg.  
Seattle 4, Wash.  
Phone ELiot 1738

### National Chinchilla Breeders Of Canada

Incorporated under Livestock Pedigree Act at the Department of Agriculture, Ottawa, Canada.

#### Invite Chinchilla Breeders

to join as Annual or Non-Resident members and receive "The National Chinchilla Breeder of Canada" (12 monthly issues) and other benefits. Membership fee — \$5.00 per year.

National Chinchilla Breeders of Canada,  
City View,  
Ontario, Canada.

Print Name \_\_\_\_\_

Print Address \_\_\_\_\_

## Mink Production

(Continued from Page 4)

on this ranch was that the testes of the male approached normal size about the first week in May. Whether this was the natural result of the withdrawal of some ingredient in the feed or of the feeding of the iodinated casein referred to before is not provable under the circumstances for feeding of the suspected poultry waste was discontinued when iodinated casein was added to the diet.

#### Partial Failure

Poultry waste, some of which came from "caponettes," fed during the winter and spring but not continuously resulted in erratic breeding behavior and in some implantations but in the birth of but one kit. Animals that had been brought to this farm a few weeks before the breeding season reproduced normally. The kit was examined late in June and appeared to have been born very late in the season. The writer would judge that it arrived nearer June 1 than May 1. From mink that were palpated it appeared that some of the mink had become pregnant but the kits were dead. This is an interesting observation in view of the fact that this herd seems to have had a light dose of diethylstilbestrol and that intermittently. Under such conditions fertilization apparently takes place, implantation follows, but the kits die before birth. It has not been proved that diethylstilbestrol will cause mink kits to die before birth, but this is indicated by the high percentage of females receiving chicken waste from "caponettes" that became pregnant only to resorb their young. In sizeable dosages the hormone affects the growing follicles, but at a low rate of administration the fol-

licle is not damaged to such an extent that ovulation is impossible. Nevertheless, no kits are born because the egg though fertilized, does not develop. The possibility that resorption was caused by a direct effect of the hormone on the embryo or placenta cannot be overlooked, but direct evidence that it affects either the embryo or the placenta is lacking.

Another deduction that can be made from the experience on this ranch is that low levels of feeding, kept low more by the fact that the hormone was fed only periodically than by dilution, does not sterilize all the male all the time. Otherwise it would be difficult to explain how so many of the females became pregnant even though they were not able to carry kits through to birth.

#### Effect on Breeding Stock

Disastrous as the feeding of diethylstilbestrol is to current production, the one ray of hope to the rancher who has suffered is the fact that many of his breeding animals will produce if kept over to the next breeding season. Several ranchers have kept over mink that failed to breed after feeding poultry waste suspected of containing material from "caponettes." On one farm of 16 females that had borne litters before they were fed the hormone, 9 produced litters while 19 females fed the waste when they were kits produced only 5 litters. This is in keeping with histological observations made on ovaries secured at pelting time, which indicated that the ovaries of some of the kits appeared to be injured beyond regeneration. On another farm 80 litters were produced by 121 females but these were not classified into adult and kit females. Apparently the Aleutians are affected more than are other mink, but because of the small numbers involved it is not safe to say that this is due to the same factor or factors that had caused the trouble originally.

Males as well as females may return to normal breeding condition after the feeding. Apparently the percentage of sterility is not much higher than that found among untreated males.

The feeding of poultry waste containing diethylstilbestrol has other interesting physiological results but these will not be discussed here.

WILL LET 75 HYBRID ALEUTIAN FEMALES, MALES, ON SHARES TO DEPENDABLE RANCHER.

HERBERT MARTY

1141 N. E. 21st St.

Portland Ore.

Phone MURdock 1221

DR. E. A. SCHMOKER  
VETERINARIAN

SPECIALIZING IN SMALL ANIMALS  
INCLUDING MINK

13047 Bethell Way  
(Lake City)

Seattle 31  
Phone EMerzon 0303

## AT LAST

### An Answer To Your Feeding Problems

Perhaps you are having difficulty obtaining liver and glandular meats, a source of the essential Animal Protein Factor "APF."

If so, your answer can be found in FUR-BREEDERS-AYD. A new supplement formulated to replace these essential meat products.

FUR-BREEDERS-AYD is fortified with a source of milk factors and fish livers. These products contain the "APF" complex from NATURAL sources plus fermentation products that assure ample vitamin B-12 activity and other growth factors including antibiotics. FUR-BREEDERS-AYD is also fortified with vitamins A&D, riboflavin and factors of the B-G complex, including a source of folic acid and the essential protein amino acids.

FUR-BREEDERS-AYD

Accessory Food for Fur Bearing Animals

— Write for free pamphlet —

WILLIAMS DISTRIBUTING CO.

1906 N. E. 57th Ave.

Portland, Oregon

# **APPENDIX 4**

# THE ANATOMICAL RECORD

## MANAGING EDITOR

EDWARD A. BOYDEN  
University of Minnesota

## ASSOCIATE EDITORS

CHARLES H. DANFORTH  
Stanford University

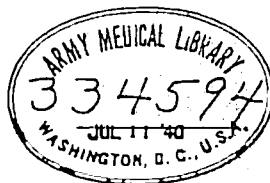
B. C. H. HARVEY  
The University of Chicago

PHILIP E. SMITH  
Columbia University

HAROLD L. WEATHERFORD  
Harvard University

VOLUME 74

MAY, JUNE, JULY, AUGUST, 1939  
AND SUPPLEMENT NO. 1



THE WISTAR INSTITUTE OF ANATOMY AND BIOLOGY  
PHILADELPHIA, PA.

## EXPERIMENTAL INTERSEXUALITY

### THE PARADOXICAL EFFECTS OF ESTROGENS ON THE SEXUAL DEVELOPMENT OF THE FEMALE RAT <sup>1</sup>

R. R. GREENE, M. W. BURRILL AND A. C. IVY

*Department of Physiology and Pharmacology, Northwestern University  
Medical School, Chicago*

#### EIGHT FIGURES

The feminizing effects of estrogens on the sexual differentiation of genetic male rats has been reported (Greene, Burrill and Ivy, '38 a, '39 a). Estradiol and estradiol dipropionate were given to pregnant rats. The male offspring were feminized in that development of the epididymis, vas deferens and seminal vesicle was inhibited and prostates were absent; a vagina, parts of the uteri and nipples were present.

In the earlier report it was stated that the females of these litters showed some gross changes from the normal. These changes were: precocious development of nipples, gross enlargement of the uteri and inhibition of the ovarian capsule. Since this report, twenty-one of these females have been serially sectioned and studied in detail. The findings are paradoxical in that the development of certain female structures is inhibited and certain structures characteristic of the male are present.

#### PROCEDURE

The estradiol and estradiol dipropionate <sup>2</sup> were given subcutaneously in oil solution to the pregnant rats. The total dosages used and the periods of pregnancy during which

<sup>1</sup> Supported in part by a grant from the Josiah Macy Jr. Foundation.

<sup>2</sup> The alpha estradiol and estradiol dipropionate were generously supplied by Dr. Ernst Oppenheimer of Ciba Pharmaceutical Products.

TABLE 1

LITTER NO.	TOTAL DOSAGE	DAYS OF TREATMENT	STATUS OF WOLFFIAN DUCTS R L		BIFURCATION OF VAGINA	SEM. YRS. ANLAGER
Alpha estradiol						
79-C	0.8 mg.	13-20	Cranial remn. Ej. duct remn.	Cranial remn. Ej. duct remn.		Abs.
291-B	7.5	13-20	Not pres.	Almost comp. Part. pat.	Bifurcated	Pres.-L
256-B	10.0	13-17	Comp. and pat.	Comp. and pat.	Bifurcated	Pres.-R
Estradiol dipropionate						
192-A	2.0	14	Almost comp. Part pat.	Intermittent	Bifurcated	Pres.-R
202	3.25	13-17	Cranial rema. Ej. duct rema.	Cranial remn. Ej. duct remn.	Not bifurcated	Abs.
225-A	5.0	13-17	Ej. duct remn. (fused with vagina)	Ej. duct remn. (fused with vagina)	Not bifurcated	Abs.
230-A	7.0	12-16	Cranial remn. Ej. duct remn.	Cranial remn. Ej. duct remn.	Not bifurcated	Abs.
246-A	10.0	13-18	Cranial remn. Ej. duct remn.	Cranial remn. Ej. duct remn.	Not bifurcated	†
282-B <sup>1</sup>	10.0	13-17	Ej. duct remn.	Ej. duct remn.	Not bifurcated	Abs.
254	13.0	13-17	Almost comp. Patent	Cranial remn. Ej. duct remn.	Bifurcated	Abs.
257-B	20.0	13-19	Cranial remn. Ej. duct remn.	Cranial remn. Ej. duct remn.	Bifurcated	Abs.
276-A <sup>1</sup>	20.0	13-17	Ej. duct rema.	Almost comp. Part patent.	Bifurcated	Abs.
288-C <sup>2</sup>	20.0	13-19	Cranial remn.	Cranial remn. Lower half pres. and patent	Not bifurcated	Abs.
271	22.0	12-21	Not pres.	Not pres.	Not bifurcated	Abs.
265-A	25.0	13-19	Intermittent	Intermittent	Bifurcated	Abs.
266-A	25.0	13-19	Comp. and pat.	Intermittent (part pat.)	Bifurcated	Pres.-R
272-A	35.0	13-17	Cranial remn. Ej. duct rema.	Almost comp. Part patent	Bifurcated	Pres.-L
277-A	50.0	13-17	Almost comp. Part patent.	Intermittent	Bifurcated	Abs.
279-A	60.0	13-17	Cranial rema. Ej. duct remn.	Almost comp. Part patent	Not bifurcated	Abs.
280-A	80.0	13-17	Cranial remn. Ej. duct remn.	Cranial remn. Ej. duct remn.	Bifurcated	Abs.
284-A	100.0	13	Intermittent Part patent	Intermittent Part patent		Abs.

<sup>1</sup> Mother bilaterally adrenalectomized on thirteenth day of pregnancy.<sup>2</sup> Mother unilaterally castrated on thirteenth day of pregnancy.

treatment  
estradiol  
divided  
of treat  
carrying  
After  
day of  
colony),  
were kil  
Since th  
external  
several  
maining

Stimul  
found in  
the four  
but in th  
present  
thread-li  
base of th  
fuse to f  
uteri are  
times gre  
and meas  
due to ac  
There is  
which is  
Inhibit  
modified  
is almost  
modified  
sequently  
capsule i  
by giving  
Burrill a

## EXPERIMENTAL INTERSEXUALITY

431

BIFURCATION OF VAGINA	SEM. VES. ANLAGE
--------------------------	---------------------

Abs.

bifurcated	Pres.-L
bifurcated	Pres.-R

bifurcated	Pres.-R
------------	---------

not bifurcated	Abs.
----------------	------

not bifurcated	Abs.
----------------	------

not bifurcated	Abs.
----------------	------

not bifurcated	†
----------------	---

not bifurcated	Abs.
----------------	------

bifurcated	Abs.
------------	------

bifurcated	Abs.
------------	------

bifurcated	Abs.
------------	------

not bifurcated	Abs.
----------------	------

not bifurcated	Abs.
----------------	------

bifurcated	Abs.
------------	------

bifurcated	Pres.-R
------------	---------

bifurcated	Pres.-L
------------	---------

bifurcated	Abs.
------------	------

not bifurcated	Abs.
----------------	------

bifurcated	Abs.
------------	------

	Abs.
--	------

treatment was administered are tabulated (table 1). The estradiol dipropionate was administered in both single and divided doses, the estradiol in divided doses only. The effects of treatment on the mother and the percentage of animals carrying to term will be reported later.

After delivery by cesarian section on the twenty-second day of pregnancy (the usual time of parturition in our rat colony), at least one male and one female from each litter were killed and examined under a dissecting microscope. Since the males and females of the higher dosage litters are externally identical it was sometimes necessary to sacrifice several animals in order to obtain one of each sex. The remaining young were given to foster mothers.

## OBSERVATIONS

Stimulation of certain normal female structures has been found in all of these females. Normally nipples appear about the fourth day postpartum in the female rats of our colony, but in the modified females large, well-developed nipples are present at birth. In the normal newborn the uteri are thin, thread-like structures extending from the ovaries at the caudal base of the kidney to behind the base of the bladder where they fuse to form the vagina (fig. 1). In the modified females the uteri are grossly thickened, the diameter being two to three times greater than normal (fig. 2). Microscopic examination and measurements definitely prove that this enlargement is due to actual growth as well as to distention by secreted fluid. There is also some enlargement of that portion of the vagina which is present (figs. 3 and 4).

Inhibition of normal female structures also occurs in these modified females. Normally the ovary of the newborn female is almost completely covered by the ovarian capsule. In the modified animals the ovarian capsule is lacking and consequently the gonads are bare. This absence of the ovarian capsule is also found in the masculinized females produced by giving large doses of androgens to the pregnant rat (Greene, Burrill and Ivy, '38 b, '39 b). Development of the lower

vagina is also inhibited in the modified females. Normally longitudinal fission of the urogenital sinus into urethra and lower vagina is almost complete at birth, only the caudal part of the vagina remains attached to the urethra by a

## ABBREVIATIONS

B., bifurcation of upper vagina  
E.D., ejaculatory duct  
EF., efferent tubules  
O., ovary  
OV., oviduct

S.V., seminal vesicle  
U., urethra  
UT., uterus  
V., vagina  
W.D., wolffian duct

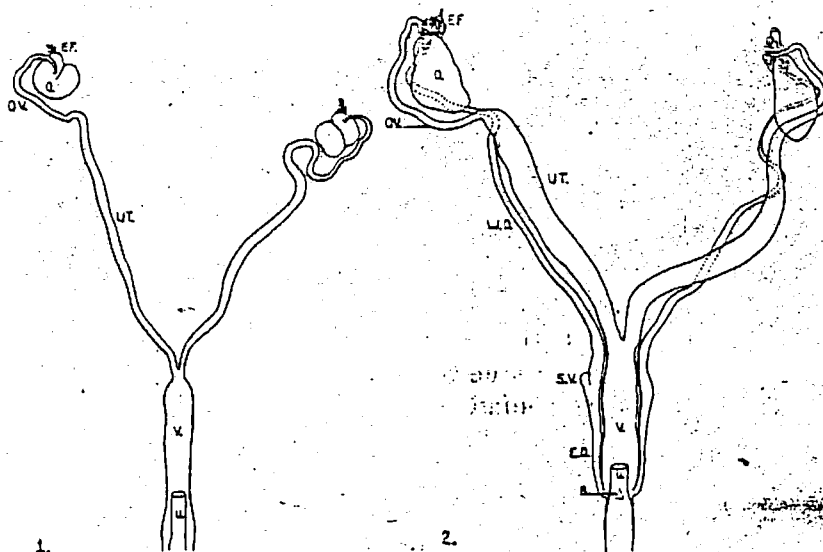


Fig. 1 Normal newborn female. Sketch made from graphic reconstruction.

Fig. 2 286-B. Newborn female. Mother received 10 mg. of estradiol during the thirteenth to seventeenth days of pregnancy.

bridge of epithelial cells. In the experimental animals the fission process has been inhibited so that the lower vagina is only partially separated from the urethra. In some cases the extreme caudal part of the lower vagina is not formed at all. This inhibition of vaginal development is similar to, but less extensive than that found in the masculinized females obtained by giving androgens to the pregnant rat (Greene,

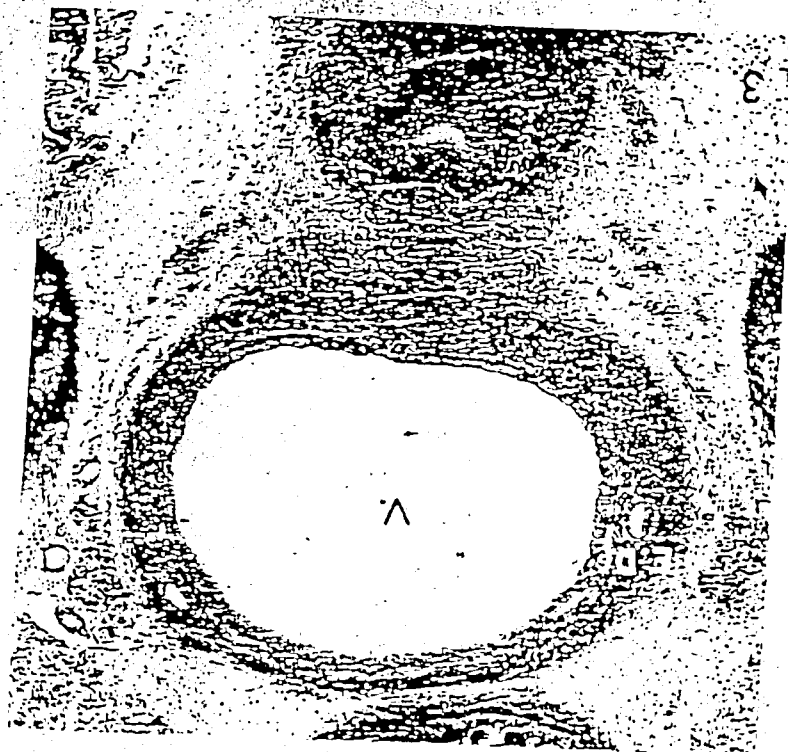
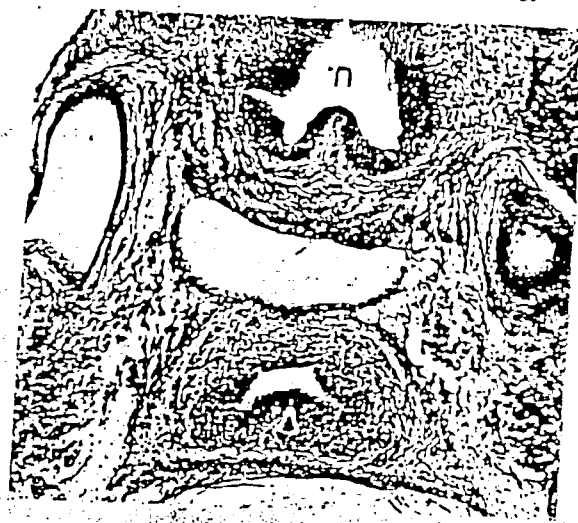
Fig. 3 286-A. accompanying ejaculatory duct on thirteenth to sixteenth days of pregnancy.  
Fig. 4 Normal

THE ANATOMICAL RECORD, VOL. 14, NO. 4

433

Fig. 3 266-A. Newborn female. Section through upper vagina showing accompanying ejaculatory ducts. Mother received 25 mg. estradiol dipropionate on thirteenth to nineteenth days of pregnancy. X 75.

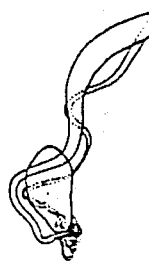
Fig. 4 Normal newborn female. Section through upper vagina. X 75.



Normally urethra and the caudal ethra by a

vesicle

duct



struction. adiol during

mals the vagina is ne-cases. rmed at ilar to, females, Greene,

CV

Burrill and Ivy, '38 b, '39 b). Another abnormality in vaginal development has been noted in some of the modified females. At the level where the upper vagina is continuous with the lower, the upper vagina is bifurcated. This condition probably represents an inhibition or arrest of normal development. Normally the upper vagina is formed by the fusion of the müllerian ducts. The extreme caudal portions of the ducts, where they join the urogenital sinus, remain separate as late as the twenty-first day. Between the twenty-first and twenty-second days they fuse so that at birth the transition point between the upper and lower vagina is not apparent. This final fusion has failed to occur at the proper time in the modified females so that the caudal end of the upper vagina is bifurcated (fig. 2). Whether or not this bifurcation disappears after birth is not yet known.

Besides these effects, both stimulatory and inhibitory, on various female structures, some stimulation of male structures is evident in the modified females. Normally, in the female, the wolffian duct starts to regress on the seventeenth day of development and continues on subsequent days until, on the twenty-first day, only two remnants remain. One remnant, usually very small, is situated cranially and is continuous with the efferent tubules; the other is located caudally and represents the homologue of the male ejaculatory duct. This caudal remnant ordinarily becomes involved in the formation of a small portion of the vagina and is not present as a discrete structure at birth. In the modified newborn females, wolffian ducts have been found in various states of preservation. In some, only the caudal remnants are preserved as

Fig. 5 Normal newborn female. Section of uterus.  $\times 75$ .

Fig. 6 266-A. Newborn female. Section of uterus and accompanying wolffian duct.  $\times 75$ .

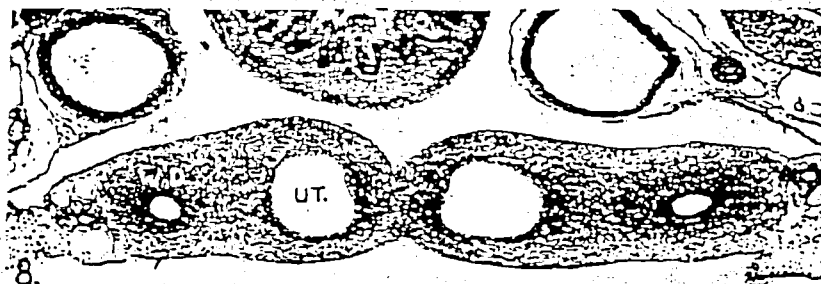
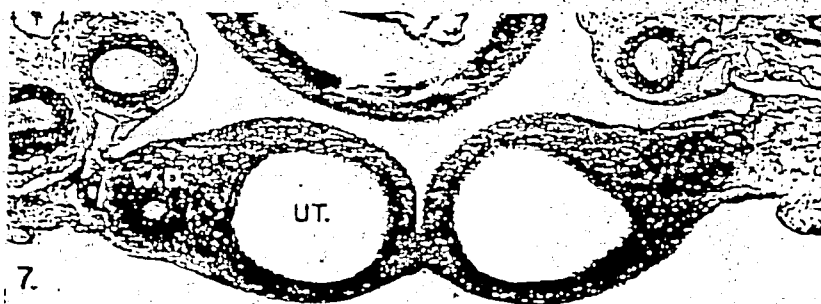
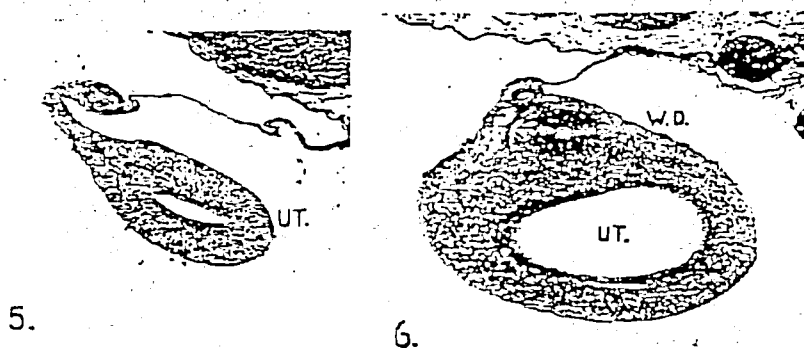
Fig. 7 266-A. Newborn female. Section through uteri. Right wolffian duct is well developed and patent, left wolffian duct non-patent. Mother received 25 mg. estradiol dipropionate on thirteenth to seventeenth days of pregnancy.  $\times 75$ .

Fig. 8 286-B. Newborn female. Same region as shown in figure 7. Both wolffian ducts well developed and patent. Mother received 10 mg. estradiol on thirteenth to seventeenth days of pregnancy.  $\times 75$ .

## EXPERIMENTAL INTERSEXUALITY

435

vaginal  
females.  
with the  
probably  
opment.  
of the  
e ducts,  
rate as  
irst and  
ansition  
pparent.  
e in the  
vagina  
ion dis-



wolffian

han duct

d 25 mg.

X 75.

7. Both

adial on

short, solid epithelial cords which fuse with the vaginal epithelium. This condition represents the lowest degree of retention noted. More and more complete preservation of the wolffian ducts is found, culminating in complete retention of both wolffian ducts as well-developed patent structures extending from the efferent tubules, with which they are continuous, to the vagina with which they also communicate (fig. 2). True seminal vesicles have not been found in these animals, but in five animals a partial constriction of the vas has been noted at the level where the seminal vesicles normally bud off from the wolffian duct (fig. 2).

Within the dosage range which we have used to date (0.5 to 100 mg.) there has been no evidence of a correlation between the amount of estrogen administered to the pregnant rat and the degree of effect on the female offspring. This lack of correlation is somewhat surprising in view of the fact that the degree of masculinization of female offspring obtained by the administration of androgens to the pregnant rat varies directly with the dosage (Burrill, Greene and Ivy, '39). However, it is possible that when the maximum dosage of estrogens is increased beyond the present limit of 100 mg., such a correlation will become evident.

#### DISCUSSION

It may be argued that these changes in the females represent only arrested development and not true masculinization. The presence of the wolffian duct may be interpreted in this way since this duct is present in one period of normal female development. In these females its subsequent involution has been inhibited. Also, the fact that the wolffian duct is not highly differentiated in these females lends credence to this interpretation, i.e., the duct has been retained, but has not been stimulated to develop in a typically masculine manner. However, the tendency toward seminal vesicle formation found in five out of twenty-one of these females cannot be attributed to developmental arrest inasmuch as no seminal vesicular anlage occur in normal female development (Greene,

Burrill  
which  
pregnan  
in that  
inhibite  
have be

The  
the fem  
explical  
pressed  
produce  
(Greene  
sinus d  
directly  
of masc  
formati  
In the r  
develop  
are lack  
the fem  
formed.  
of the  
and fem

It sho  
employe  
There is  
are pro  
veloping  
the res  
ducts ha  
undergo  
the male  
been inh

Large  
estradio

## EXPERIMENTAL INTERSEXUALITY

437

Burrill and Ivy, '39 b). The females obtained from mothers which were treated with high dosages of estrogens during pregnancy may be considered as having been 'masculinized' in that the development of certain female structures has been inhibited and certain structures characteristic of the male have been caused to persist or to develop.

The behavior of the urogenital sinus in both the male and the female offspring of estrogen treated mothers is also inexplicable. In the female, normal development is partly suppressed so that an incomplete, poorly formed lower vagina is produced. As has been mentioned in a previous publication (Greene, Burrill and Ivy, '39 b), a similar arrest of urogenital sinus development may be caused by injecting estrogens directly into the normal newborn female rat. No evidence of masculine development of the urogenital sinus, i.e., the formation of prostates, has been found in these females. In the male offspring of estrogen treated mothers, masculine development of the urogenital sinus is inhibited, i.e., prostates are lacking, but there is a certain degree of development in the female direction inasmuch as a partial lower vagina is formed. The end result of the alterations in the development of the urogenital sinus is practically identical in the male and female offspring.

It should be emphasized that, in the experimental procedure employed, estrogens were administered to the pregnant rat. There is no proof, therefore, that the changes in the offspring are produced by a direct action of the estrogens on the developing fetuses. Whether the action is direct or indirect the results obtained are indeed paradoxical. The wolffian ducts have been caused to persist in the female and have undergone actual degeneration and partial disappearance in the male. Feminine development of the urogenital sinus has been inhibited in the female and stimulated in the male.

## SUMMARY

Large doses (0.8 to 100 mg.) of estrogens (estradiol and estradiol dipropionate) have been administered to pregnant

rats. Twenty-one newborn females have been serially sectioned and studied. In these animals there was a stimulation of certain female structures (uteri and nipples) and inhibition of other female structures (lower vagina and ovarian capsule). In twenty animals there has been partial or complete preservation of the wolffian ducts. In one animal the wolffian duct was complete on one side and in another both ducts were complete.

## LITERATURE CITED

- BURRILL, M. W., R. R. GREENE AND A. C. IVY 1939 Experimental intersexuality: correlation between treatment and degree of masculinization of genetic female rats. *Am. J. Physiol.* (Proceedings, p. 36.)
- GREENE, R. R., M. W. BURRILL AND A. C. IVY 1938 a Experimental intersexuality: The production of feminized male rats by antenatal treatment with estrogens. *Science*, vol. 88, p. 130.
- 1938 b The experimental production of intersexuality in the female rat. *Am. J. Ob. and Gyna.*, vol. 36, p. 1038.
- 1939 a Experimental intersexuality: Modifications of embryonic sexual development obtained by giving large amounts of estrogens to the pregnant rat. *Am. J. Physiol.* (Proceedings, p. 94.)
- 1939 b Experimental intersexuality: The effect of antenatal androgens on sexual development of female rats. *Am. J. Anat.* (In press.)

Although  
than one  
about 40  
Schulze,  
staining pr  
Bensley as  
teems with  
various fix  
tained with  
and many  
wonder the  
components  
have not be

For exam  
strictly to l  
tion preven  
other hand,  
Zenker sol  
mental pap  
fixed by al  
chromate-s  
lations are  
in alcoholic  
consider th

This work  
for Medical Re

# **APPENDIX 5**

# AMERICAN JOURNAL OF OBSTETRICS AND GYNECOLOGY

## ADVISORY COMMITTEE ON POLICY 1953

Willard M. Allen	Nicholson J. Eastman
John I. Brewer	Frederick H. Falls
Francis Bayard Carter	Newell W. Philpott
Conrad G. Collins	John Rock
Samuel A. Cosgrove	Donald G. Tottatson
Walter T. Dana-Reuther	Philip F. Williams

## ADVISORY EDITORIAL COMMITTEE 1953

Albert H. Aldridge	Andrew A. Marchetti	Franklin L. Payne
Edward Allen	Harvey B. Matthews	Lawrence M. Randall
Allan C. Barnes	John L. McKelvey	Duncan E. Reid
Leroy A. Calkins	Charles E. McLennan	Ralph A. Reis
Russell R. de Alvarez	Joe Vincent Meigs	Herbert E. Schmitt
R. Gordon Douglas	William F. Mangert	George V. Smith
George H. Gardner	Norman F. Miller	Wm. E. Studdiford
Carl P. Huber	Thaddeus L. Montgomery	E. Stewart Taylor
Frank B. Lock	Daniel G. Morton	Richard W. Te Linds
Curtis J. Lund	Emil Novak	Herbert F. Traut
	Ernest W. Page	

## OFFICIAL ORGAN

THE AMERICAN GYNECOLOGICAL SOCIETY; THE AMERICAN ASSOCIATION OF OBSTETRICIANS, GYNECOLOGISTS AND ABDOMINAL SURGEONS; NEW YORK OBSTETRICAL SOCIETY; OBSTETRICAL SOCIETY OF PHILADELPHIA; BROOKLYN GYNECOLOGICAL SOCIETY; ST. LOUIS GYNECOLOGICAL SOCIETY; NEW ORLEANS GYNECOLOGICAL AND OBSTETRICAL SOCIETY; THE OBSTETRICAL AND GYNECOLOGICAL SOCIETY OF MARYLAND; CHICAGO GYNECOLOGICAL SOCIETY; CINCINNATI OBSTETRIC SOCIETY; CENTRAL ASSOCIATION OF OBSTETRICIANS AND GYNECOLOGISTS; AMERICAN BOARD OF OBSTETRICS AND GYNECOLOGY; WASHINGTON GYNECOLOGICAL SOCIETY; PITTSBURGH OBSTETRICAL AND GYNECOLOGICAL SOCIETY; OBSTETRICAL SOCIETY OF BOSTON; LOUISVILLE OBSTETRICAL AND GYNECOLOGICAL SOCIETY; SOUTH ATLANTIC ASSOCIATION OF OBSTETRICIANS AND GYNECOLOGISTS; SEATTLE GYNECOLOGICAL SOCIETY; SOCIETY OF OBSTETRICIANS AND GYNECOLOGISTS OF CANADA; ALABAMA ASSOCIATION OF OBSTETRICIANS AND GYNECOLOGISTS; ARIZONA OBSTETRICAL AND GYNECOLOGICAL SOCIETY; KANSAS CITY GYNECOLOGICAL SOCIETY; CENTRAL NEW YORK ASSOCIATION OF GYNECOLOGISTS AND OBSTETRICIANS; NEW JERSEY OBSTETRICAL AND GYNECOLOGICAL SOCIETY; IOWA OBSTETRIC AND GYNECOLOGICAL SOCIETY; THE TEXAS ASSOCIATION OF OBSTETRICIANS AND GYNECOLOGISTS; OKLAHOMA CITY OBSTETRICAL AND GYNECOLOGICAL SOCIETY; MEMPHIS OBSTETRICAL AND GYNECOLOGICAL SOCIETY; UTAH OBSTETRICAL AND GYNECOLOGICAL SOCIETY; ROCHESTER OBSTETRICAL AND GYNECOLOGICAL SOCIETY

## EDITORS

HOWARD C. TAYLOR, JR., and WILLIAM J. DIECKMANN

ADVISORY EDITOR  
GEORGE W. KOSMAH

VOLUME 66  
JULY-DECEMBER, 1953

THE C. V. MOSBY COMPANY  
ST. LOUIS  
1953

Volume 66  
Number 3DOES THE ADMINISTRATION OF DIETHYLSTILBESTROL DURING  
PREGNANCY HAVE THERAPEUTIC VALUE?†W. J. DIECKMANN, M.D., M. E. DAVIS, M.D., L. M. RYNKIEWICZ, S.M., AND  
R. E. POTTINGER, S.M., CHICAGO; ILL.*(From the Department of Obstetrics and Gynecology of the University of Chicago and the  
Chicago Lying-in Hospital)*

IN 1946 Smith and Smith<sup>1</sup> suggested that increasing amounts of diethylstilbestrol should be administered to all women during pregnancy to prevent or decrease the hazards of the late complications of pregnancy for mothers and babies. The basis for such prophylactic therapy as well as the active therapy of these pregnancy complications stems from a series of experiments by the Smiths on the steroid hormones in normal and abnormal pregnancy. These laboratory observations and their theoretical implications were supported by clinical observations, part of which were made under the supervision of the Smiths and part were the collected reports of other clinical observers.

The use of diethylstilbestrol to prevent and to treat pregnancy complications is based on the supposition that there develops a deficiency in the production of progesterone and other steroids by the placenta which predisposes to or causes these pregnancy complications. The secretion of these steroids can be stimulated by diethylstilbestrol. The increased amounts of steroids made available by the placenta postpone, reduce the severity of, or prevent some of the late complications of pregnancy.

The laboratory experiments which provided the background for this interesting concept of the Smiths have lacked confirmation by other investigators. Davis and Fugo<sup>2</sup> in two reports noted that the administration of diethylstilbestrol to patients during pregnancy did not result in an increased output of urinary pregnanediol, a measure of progesterone metabolism. Sommerville, Marrian and Clayton<sup>3</sup> confirmed these observations and noted a drop in urinary pregnanediol and no gross change in endogenous estrogen. Although many additional experimental data will be necessary to determine the role of diethylstilbestrol in placental steroid metabolism, this paper will confine itself to the clinical implications of the Smith concept.

Smith and Smith in 1949<sup>1</sup> reported on the influence of diethylstilbestrol on the progress and outcome of pregnancy in a series of primigravidas. As

\*This investigation was supported in part by a research grant, PHS RG3370, from the National Institutes of Health, Public Health Service.

†Presented at the Seventy-sixth Annual Meeting of the American Gynecological Society, Lake Placid, N. Y., June 15 to 17, 1951.

controls they used. They recorded the late toxemias usually large for was decreased. (4) decreased. (5) Th

The most serious Patients to whom meticulous study ously. In two out patients who were co instructions, keep dence of abortion, a lower perinatal women delivered were compared with received identical t significant difference

The prophylactic use in pregnancy co to postpone, or to mothers and babies plished by the daily a careful perusal of not supported by ad

The properly co should have no know of patients should r the medication on t treated simultaneous cently reported by that diethylstilbestre maturity, perinatal a

We felt that it clinical experiment to practice. The first p study terminated Nov

The following ci large so that the res of patients who were was decided that 2,000 prior to the twentieth Every other patient v sonal element, each p individual who was n

1074

DIECKMANN ET AL.

Am. J. Obst. & Gynec.  
November, 1951Volume 55  
Number 5

Since our data were at variance with those of the Smiths, they were all rechecked. The charts of patients with toxemia of pregnancy, premature delivery, stillbirths and neonatal deaths, and any other complication or abnormality, were examined again by one of the senior authors with no knowledge of the kind of medication. There was no significant change in any of the results.

TABLE IX. CONGENITAL ANOMALIES

TYPE OF ANOMALY	PRIMIPARAS		MULTIPARAS	
	STILBESTROL	CONTROL	STILBESTROL	CONTROL
Minor	7	7	9	4
Skin, as papilloma	7	12	7	5
Cystocele, hydrocele	4	3	3	2
Harelip, cleft palate, etc.	1	0	0	1
Clubfoot, multiple digits	2	5	5	3
Mongolism	0	0	0	1
Brain and spinal cord	1	0	0	0
Cardiac, etc.	2	1	1	2
Gastrointestinal	1	0	0	0
Genitourinary	0	2	0	3
Multiple major	2	2	1	1
Total anomalies	27	32	27	24
Total infants	425	415	376	361

## Conclusions

A strictly controlled clinical trial of the therapeutic value of diethylstilbestrol administered to patients during pregnancy in reducing the hazards of some of the late complications of pregnancy for mothers and babies has been reported.

The various complications were studied in the total unselected group of patients divided into primigravidas, primiparas, and multiparas. Then the groups were again studied after all groups were corrected to compare with the Smiths'.

The results of the administration of diethylstilbestrol in graduated amounts to 840 patients according to a schedule suggested by the Smiths were compared with the results of an identical placebo tablet given to 806 patients. Stilbestrol did not reduce the incidence of abortion, prematurity, or postmaturity. Premature babies of stilbestrol-treated mothers were no longer nor more mature for their gestational ages than comparable prematures in the control group of placebo-treated mothers. It did not decrease the incidence of perinatal mortality. It did not decrease the frequency of the toxemias of pregnancy.

Acknowledgment is made to Eli Lilly and Company for aid in making the stilbestrol and placebo tablets with the dye and for the final determination of the stilbestrol; to Lillian Natunsko for the examination of the urines for phenol red; to the staff and residents for their cooperation.

## References

1. Smith, O. W., and Smith, G. van S.: *Am. J. Obst. & Gynec.* 51: 411, 1946.
2. Smith, G. van S., and Smith, O. W.: *Physiol. Rev.* 23: 1, 1943.
3. Davis, M. Edward, and Fugo, N. W.: *Proc. Soc. Exper. Biol. & Med.* 65: 283, and 56: 391, 1947.

4. Davis, M.
5. Sommer
6. Smith, O.
7. Dieckmann, M. T.
8. Gitman, I.
9. Smith, O.
10. Ferguson,
11. Canario, E.

## DR. GEC

mann and his work, and exp told us he was for a beneficia value could be planning to the Worcester, Ass who had had nancy, stated thousands of e. She advised th every season t treated group n published by I studied. To be impossible. Th We too are dis to so much trou run, their exper We also w that the only d groups lay in th teacher, who sa dentally, fully i drawal in patie conveyed this co Dr. Olive Smith. Actually, most c and, therefore, s Neither th patients was set omitted from ou those who had th our control series. who began takin phylactic value o previous abortion peatedly miscarry now are certain ing abortion, ther They includ There were more trols (23 vs. 17) pre-eclampsia. L

# **APPENDIX 6**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

KIMBERLY C. CUTONE and  
ANTHONY CUTONE.

Plaintiffs,

v.

ELI LILLY AND COMPANY, et al.,

Defendants.

Civil Action No. 04-CV-12725 (JLT)

**DEFENDANT ELI LILLY AND COMPANY'S RESPONSES TO  
PLAINTIFFS' FIRST SET OF INTERROGATORIES AND FIRST  
REQUEST FOR PRODUCTION OF DOCUMENTS AND/OR TANGIBLE THINGS**

COMES NOW defendant Eli Lilly and Company (hereinafter "Lilly"), by and through its attorneys, Foley Hoag, LLP, pursuant to Rules 33 and 34 of the Federal Rules of Civil Procedure, and provides the following responses to Plaintiff's First Set of Interrogatories and First Request for Production of Documents and/or Tangible Things to Defendant Eli Lilly and Company.

**PRELIMINARY STATEMENT**

As a preface to each and every response to plaintiffs' interrogatories and requests, Lilly qualifies its response by stating that Lilly has not completed its investigation of the facts relating to this case, has not completed its discovery in this action and has not completed its preparation for trial. Lilly reserves the right to amend or supplement these responses as discovery in the case progresses, as new facts are developed and as new information is obtained. Therefore, the following responses are given without prejudice to Lilly's right to produce any additional evidence at trial or in connection with any pretrial proceeding.

establish the elements of her alleged cause of action, including the cause of her injuries. Without waiving and subject to its objections, Lilly states that it has not completed its investigation and discovery in this matter, and cannot fully respond to this interrogatory at this time. Because such information is not within the direct knowledge of Lilly, Lilly can only respond to the extent that the information is obtained through discovery, which is still ongoing. At the present time, the witnesses identified by plaintiff may have information concerning the manufacturer(s) of any medications plaintiff Kimberly Cutone's mother allegedly ingested during her pregnancy with plaintiff.

2. Lilly Wholesalers

Identify the Lilly distributors or wholesalers serving the alleged city of exposure during the relevant time period, and describe any agreements made between you and them regarding giving preference to Lilly products, or attach the agreement(s) to your answer.

RESPONSE: Lilly incorporates herein its Objections A, B and C. Without waiving and subject to its objections, Lilly states that through the relevant time period it sold its pharmaceutical products FOB Indianapolis, Indiana to independent drug wholesalers located throughout the United States, who, in turn, sold to retail druggists. Lilly states that for the time period relevant to plaintiff Kimberly Cutone's mother's pregnancy with her, the pharmaceutical wholesalers located in the Allston, Massachusetts area who were authorized to carry Lilly's pharmaceutical products, as well as the pharmaceutical products of other manufacturers, were:

McKesson & Robbins Drug Company  
250 Turnpike Street  
Canton, MA 02021

McKesson & Robbins Drug Company  
335 Washington Street  
Woburn, MA 01801

Gilman Brothers, Inc.  
20 Freeport Street  
Dorchester, MA 02104

New England Wholesale Drug Co.  
879 Blue Hill Avenue  
Dorchester, MA 02122

Lilly no longer has records showing sales or shipments of its pharmaceutical products to particular pharmaceutical wholesalers during the period in question. Lilly did not sell pharmaceutical products directly to physicians, hospitals, or pharmacies. Further answering, Lilly states that a representative copy of the contract which would have been in effect with Lilly's wholesalers in the Allston, Massachusetts area for the time period relevant to plaintiff Kimberly Cutone's mother's pregnancy with her, is attached at Tab A.

3. Adverse Reports to the FDA

List any specific reports or studies you provided to the FDA, in any application or communication with that agency, concerning possible risks to the daughters from *in utero* DES exposure. Do not refer to your NDA but cite with specificity the particular study which provided such information.

RESPONSE: Lilly incorporates herein its Objections A, B and D. Lilly further objects to this interrogatory to the extent it assumes as true facts at issue in this lawsuit. Lilly further objects to plaintiffs' definitions and instructions to the extent they exceed the scope of the Federal Rules of Civil Procedure and seek to prevent Lilly from providing a full and accurate response. Lilly further objects to this interrogatory to the extent it seeks information concerning the thought processes of all Lilly employees; it is impossible for Lilly to answer an interrogatory involving the thought processes of its employees over many years. Lilly cannot state when any specific person at Lilly became aware of a specific article.

Lilly further objects to this interrogatory to the extent it may assume that studies using pregnant animals are necessarily meaningful with respect to pregnant women, an assumption which Lilly disputes. Whether an animal is an appropriate model for testing the

Dr. Hines further testified that the medical community was aware that animal studies involved the use of dosage regimens which far exceeded clinical dosage sizes, and the prevailing medical opinion did not consider such studies to be clinically applicable. In a 1941 report by Ronald R. Greene published in the American Journal of Obstetrics and Gynecology, Volume 42, pages 858 to 861, Dr. Greene makes the following statement regarding the effects of diethylstilbestrol on experimental animals:

The fact that tremendous overdoses of estrogens are capable of producing truly toxic effects in experimental animals is, however, not of clinical importance. There are few substances of therapeutic value which are not toxic when given in equally tremendous overdoses.

4. White Cross Score

Do you contend that in the year of exposure as set forth in the Complaint, any other manufacturer other than you, bottled or distributed DES in the dosage sizes indicated for use in prevention of accidents of pregnancy, as a round, white cross-scored, non-imprinted tablet? If your answer is yes, identify the product or the manufacturer and any documents (by date, description or custodian), upon which you rely in making this statement. For your information, it appears that the Squibb 100mg was imprinted with their name and that the Amfre-Grant was hexagonal.

RESPONSE: Lilly incorporates herein its Objection E. Lilly further objects to this interrogatory on the grounds that it is irrelevant because there is no evidence that the product allegedly ingested by plaintiff's mother was a "round, white cross-scored, non-imprinted tablet." Lilly further objects to this interrogatory to the extent it assumes that all of Lilly's diethylstilbestrol in dosage sizes indicated for use in the prevention of certain accidents of pregnancy was round, white, non-imprinted and cross-scored.

# **APPENDIX 7**



**STATEMENT OF HAROLD SPARR, R. PH.**

Harold B. Sparr declares under penalty of perjury that the following is true and correct:

1. I am a registered and licensed pharmacist in Massachusetts, New York, and California having graduated in 1951 from the Massachusetts College of Pharmacy. I have continuously and exclusively engaged in pharmacy from 1944 to the present.

2. I was the President of the Massachusetts Board of Registration in Pharmacy as well as the President of the Massachusetts College of Pharmacy Alumni Association, and as such am personally familiar with registered pharmacists in the Boston region, as well as the actual practice of pharmacy and retail pharmaceutical catalogues.

3. From the year 1944 to the present, I have worked at the following local Boston pharmacies:

- A) Sparr's Drug Store, Inc. on 635 Huntington Ave., Boston, MA. (1944-1969);
- B) Ivy Drug on Park Drive, Boston, MA (1955);
- C) Jacobson's Pharmacy on Harvard Street, Boston (Dorchester), MA. (1955-1956);
- D) Robert's Pharmacy on 360 Trapelo Road., Belmont, MA (1969-1976).

4. I was a member of Boston Association of Retail Pharmacists (now called Massachusetts Independent Pharmacists Association) from 1955 to the present. I have had the opportunity to meet with, work with, and discuss the practice of pharmacy with hundreds of pharmacists in Suffolk County, especially in Boston, over the last fifty years.

5. I am familiar with those pharmaceuticals commonly used for the care and treatment of pregnant women in the late 1960's and early 1970's in the Boston area, including Allston. I am also familiar with the pharmacy literature in the marketing of drugs in the 1960's and 1970's.

6. I am familiar with the Red and Blue Books and those publications' listings of many diethylstilbestrol (DES) manufacturers besides Eli Lilly in the 1960's and 1970's. However, while the Red and Blue Books may represent all the medications in the world, they have no relevance to the Boston areas as Lilly virtually owned that DES market in the 1960's and 1970's.

7. I am familiar with the practice of stocking and dispensing of DES in the 1960's and 1970's in Boston. In the 1960's and 1970's, generics were not popular and were disfavored in the trade since they did not have the quality control of the major brands. Because Lilly was top quality, the Lilly DES drug was inexpensive, and could be ordered from a Lilly wholesaler one bottle at a time, the drugstores in Boston stocked Lilly's DES exclusively.

8. Based upon my practice, experience, and observations of the practice of pharmacy in Allston in the 1960's and 1970's, if a woman was dispensed DES as a white, round, cross-scored tablet in 1969-1970, she would have received Lilly's Diethylstilbestrol, as that was the only popular brand at that time in pill form in that place.

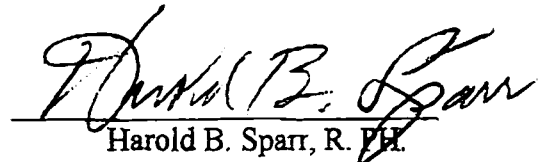
9. The import and design of the Red and Blue Books as it pertains to DES reflects a picture of the myriad and numerous regional generic bottlers of this chemical in

the various cities and localities in America representing fifty different states and over a 100 different cities.

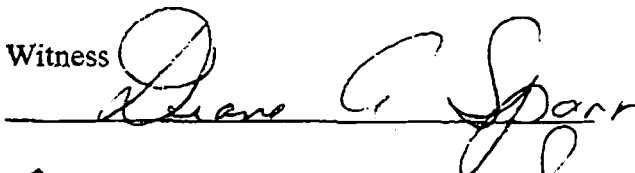
10. The Red and Blue Books do not represent nor were they designed to represent the availability of DES in the Boston market.

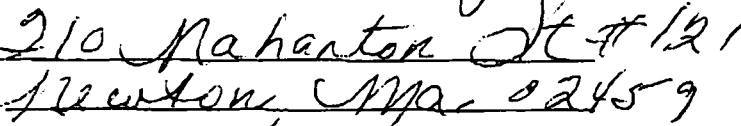
11. The great number or the great majority of the DES companies listed were not manufacturers of DES but only repackagers in local limited markets. That is, a pharmacist would repackage DES under his own label and sell it as a generic to pharmacists in this area. Of the brands listed, only a few were national pharmaceutical distributors. I.e. Lilly, Squibb, Merck, Upjohn, or Pfizer. The others were not national distributors and were not in Boston, Massachusetts. 90% of the names listed under Red and Blue Book are local generic repackagers of DES. Lilly was the Microsoft of those days.

I declare under the penalty of perjury that the foregoing is true and correct based on my personal knowledge.

  
Harold B. Sparr, R. PH.

Witness





Address

Dated: May 16, 2006

# **APPENDIX 8**



# **APPENDIX 9**

**STATEMENT OF JULIE ZHANG**

I am currently employed as a law clerk at Aaron M. Levine and Associates.

I have examined a collection of 294 photographs gathered from DES litigation and discovery during the last 30 years in our firm's archives, which depict diethylstilbestrol pills of 98 different identified, non-Eli Lilly brands. This review was conducted in order to determine if any of these non-Eli Lilly DES pills fit the description of white, round, cross-scored, and 25 mg. From my personal observations of these close-up DES pill photographs:

1. Of the 294 photographs involving 100 different brands of non-Eli Lilly diethylstilbestrol pills, there was no DES pill which was white, round, cross-scored, and 25 mg.
2. From my examination of the photographs and actual diethylstilbestrol pills manufactured by Eli Lilly, I observed that of all the DES pills I have seen, Eli Lilly & Co. is the only drug manufacturer that made a white, round, cross-scored and 25mg DES pill. This pill made by Eli Lilly was brand named, "Diethylstilbestrol" and is depicted in that attached photograph.

The above is correct and true under the penalties of perjury and is based upon my personal knowledge of the facts set forth.



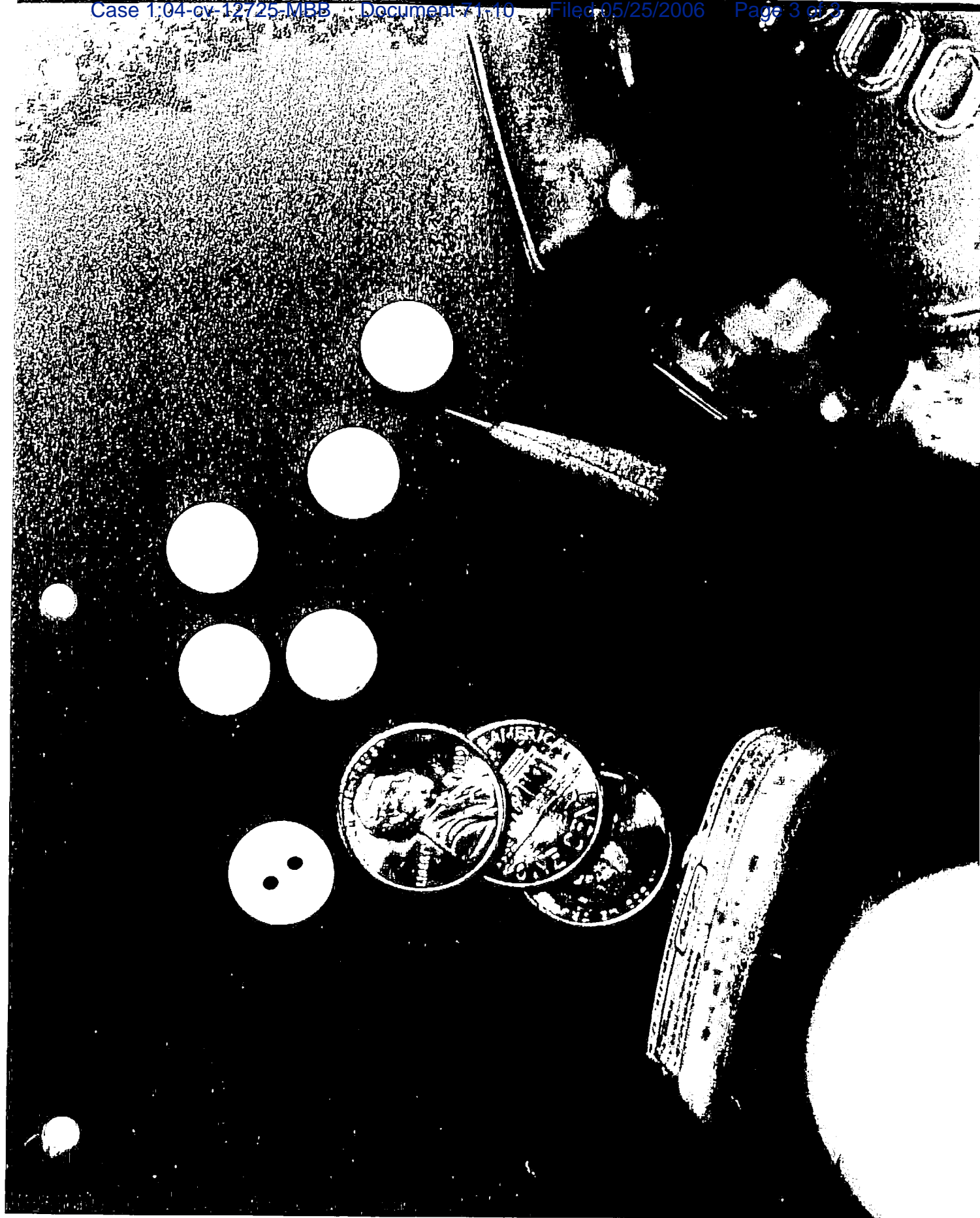
---

Julie Zhang

5/22/06

---

Date



# **APPENDIX 10**



# **APPENDIX 11**

HAROLD B. SPARR, R.PH., D.PH., M.S.

210 NAHANTON STREET, UNIT 121

NEWTON, MA 02459

TELEPHONE: (617)969-5322

October 12, 2004

Aaron M. Levine, Esq.  
Aaron M. Levine & Associates  
1320 19th Street, N.W., 5th Floor  
Washington, DC 20036

Dear Mr. Levine:

In accordance with your request of May 4, 2004, I have embarked upon a study, over the last four months, to determine the extent of the share of the pregnancy size (5<sub>mg</sub> & 25<sub>mg</sub>) DES Market (Stilbestrol - - Diethylstilbestrol) dispensed in the drug stores, in the Commonwealth of Massachusetts, for the 16 year period centered in 1965, i.e., 1955 to 1971. The six research areas which provide the basis of my opinion are:

1. My personal experience as a retail practicing pharmacist dispensing DES and teacher of pharmacy in Massachusetts over the last forty-nine years, including my experience as president of the Massachusetts Board of Registration in Pharmacy and my presidency of the Massachusetts College of Pharmacy Alumni Association.
2. Personal conversations, research and investigations, wherein I have contacted hundreds of Massachusetts pharmacists who were practicing retail pharmacy during the period of time under investigation.
3. A review of approximately 200 sworn, randomly collected Statements obtained by your office and by me over the last few years, of the recollection of over 200 retail Massachusetts pharmacists who were practicing in the period under review, including the deposition testimony and sworn statements of a wholesale pharmacist and discussions with wholesalers, as well as the dozens of actual prescriptions for DES we were able to find.
4. A literature search of the pertinent pharmacy and retail pharmaceutical literature covering the period under examination; and

Aaron M. Levine, Esq.

Page Two

October 12, 2004

5. A study employing standard survey and accepted academic bio-statistical analysis conforming to proper questionnaire, reporting and analysis practices, with the assistance of professional survey personnel.
6. A review of the Massachusetts retail drug store practices and DES marketing environment over the period 1954 to 1971, to determine year to year consistency, in order to determine if the practices were stable during the period under review, statewide, including:
  - a. Economic factors;
  - b. Social and cultural factors;
  - c. Competitive factors;
  - d. Technological change;
  - e. Government and legal factors;
  - f. Communication within the retail pharmacy industry;
  - g. Disease incidences;
  - h. Distribution of goods and services;
  - i. Demographic factors;
  - j. Physician prescribing habits;
  - k. Wholesaler and manufacturer services, distribution, support and literature;
  - l. Pharmacist education;
  - m. Packaging and delivery of pharmaceuticals;
  - n. Year-to-year innovation;
  - o. Medical indications;
  - p. Marketing and sales practice and demand;
  - q. Deletion and addition to drug popularity;
  - r. Product life cycle and shelf life;
  - s. Prescriber motivation and prescribing habits;
  - t. New drug promotion - old drug withdrawal;
  - u. Sources of information to the retail pharmacist;
  - v. Pharmaceutical product development and popularization;
  - w. F.D.A. involvement;
  - x. Market characteristics;
  - y. Generics v. brand names; and
  - z. Stability of the marketplace;

In conducting the survey, I took into consideration the market, product availability, diversification and specialization. I looked at the topics from the standpoint of the manufacturer, the wholesaler and the retailer. I considered competition in the retail pharmaceutical industry,

Aaron M. Levine, Esq.

Page Three

October 12, 2004

price determination, advertising, detailing and other forms of promotion, as well as staffing, acquisition of businesses, brand image, detailing, promotion, regulations, publications, professional standards, attitudes, nature of drug store and retail pharmacy practices, such as independence, traditional goods, sales and discounts, consumer attitudes, competition, promotion and pharmacy ethical and professional responsibilities during the '50s and '60s. I also investigated and researched prescription habits, record keeping, product variation, wholesaler to retailer supply systems, trademark and generic names, hospital verses retail operations, stocking and dispensing practices and sales and sales record keeping.

Virtually the only body of information I did not have access to was the Lilly Digest, which was a compilation published annually by Eli Lilly during that period, which covered such topics as average volume, prescription charges, costs of goods sold, expenses, new prescriptions, refills and advertising at the retail level. I understand this research is included in the Lilly Digest, which the Company has been requested to open but has not seen fit to share with us.

My qualifications for this survey are:

I began my career in retail pharmacy in 1944, as a clerk and stock boy in my father's retail pharmacy, Sparr's Drug Store, Inc., which was across the street from the Boston Lying-In Hospital and adjacent to the Harvard Medical School and the Harvard School of Public Health. As you know, DES was popular in Massachusetts, as the Smith's and other promoters lived there through the Lilly detailmen, Jason Goldsmith and Harry Fine and Louis Bromberg.

From the age of 10 until I was 17, I was a stock boy, pharmacist's assistant and would unpack orders and stock the shelves from the drug wholesalers. In 1951 at the age of 17, I became a pharmacy student at Massachusetts College of Pharmacy and Health Sciences but continued to work in the store 20 or 30 hours a week as I had for the prior seven years. While in pharmacy school, I continued to work at the store part-time as an apprentice pharmacist from the years 1951 to 1955 and thereafter, engaged in the field of pharmacy continuously and exclusively until the present, except for two years of military service as a pharmacist. I hold a Bachelor of Science Degree in Pharmacy from the Massachusetts College of Pharmacy and I am registered in Massachusetts, New York and California. I hold a Masters in Health Care Management from Pacific Western University.

My employment in the field of pharmacy has given me the opportunity to observe the retail stocking of drugs primarily because of the store's proximity to the Boston Lying-In Hospital (where DES prescribing obstetricians were located), and therefore am conversant with the manner and method of prescription of DES in the 1950s and 1960s by those obstetricians in the Boston area who popularized this drug. Boston Lying-In Hospital was the main Obstetrics

Aaron M. Levine, Esq.

Page Four

October 12, 2004

hospital in Boston in the 1950s and 1960s as it was the Harvard teaching hospital where Smith and Smith popularized Stilbestrol for the use in preventing accidents of pregnancy.

During the 1950s and 1960s, I maintained close relationships with Lilly detailmen, and Gilman & McKesson wholesalers and actually and frequently ordered, stocked and dispensed DES. As a practicing pharmacist and active participant in pharmacy affairs, I was conversant with other pharmacists in the Boston area. At this time I had the opportunity to fill prescriptions for Stilbestrol and am familiar with the physician prescribing habits, pharmacy standard of care, usual and routine pharmaceutical brands dispensing and stocking.

#### Personal familiarity with DES stocking and Dispensing:

I am familiar with Diethylstilbestrol, also known as DES and Stilbestrol, as a hormone used in pregnancy. I filled on the average of three or four prescriptions a week for DES starting in the late 1950s, I have seen it on the shelves in many other pharmacies since 1951. I knew it was indicated for prevention of miscarriage, among other uses, and I knew it came in different strengths from .1 mg to 25 mg and in white uncoated tablets as well as red-coated pills. Diethylstilbestrol was the only popular oral hormone medication given in the 1950s and 1960s to pregnant women. In the Boston area it was the drug of choice and the standard treatment for pregnant women and the only popular oral medication regularly used for this purpose. I am familiar with the Lilly publication "De Re Medica" that was sent to the physicians of America, which advocates DES as the best medication for avoiding miscarriage. I know that physicians in Massachusetts received this Lilly publication as well as P.D.R. and the other publications.

#### The consistency of DES marketing 1955 to 1971:

I have reviewed the commercial DES literature including PDR, Red Book, Blue Book, manufacturer brochures, and U.S. Pharmacopoeia from the 1950s and 1960s. I have also reviewed Lilly publications in general from the 1950s and 1960s, such as field reference manuals, product labeling, inserts, product brochures, Title and Till and other Lilly publications regarding competitive pharmaceutical manufacturers. I have reviewed a host of literature as set forth in Exhibit 6 and consulted additional texts set forth therein. I was familiar with this material in the 1950s, 1960s and 1970s. From these readings as well as my observations of the practice of pharmacy, I observed the changes occurring in the marketing, ordering, stocking and dispensing of retail pharmaceuticals over the last half century, with special focus on DES. These practices have remained relatively stable during the last 1950s and 1960s. In addition to those text and journals attached as Exhibit 6 and the Lilly publications attached as Exhibits 12, 13, 14 and 16, I have reviewed other documentation concerns with DES marketshare including:

Aaron M. Levine, Esq.  
Page Five  
October 12, 2004

1. Affidavit of Philip Cafferty a pharmacist and Lilly sales manager and detailman, Appendix 18.
2. The DES Matrix, as it evolved in the New York and California litigation. (Appendix 17).
3. The sworn Statement of John P. Della Volpe, an employee with the McKesson and Robins Company one of the largest Lilly wholesalers. (Appendix 20).
4. A dozen depositions of practicing pharmacists in this period on the question of brand identification.

I have reviewed the expected testimony of Lilly's expert's Keith Leffler, Raymond A. Gosselin, Benjamin P. Sachs, M.D. and Lynne Silvia (Appendix 5) and their conclusions that Lilly held 30 to 34% of the DES market for the pregnancy size DES which is without any basis for the following reasons:

1. Mr. Gosselin is dead; and
2. Dr. Sachs' study design is flawed.

I reviewed the following text regarding retail pharmacists.

1. Alreck and Settle, *The Survey Research Handbook*, 2nd Ed.;
2. Smith, in *Principles and Pharmacy Marketing*, Lea and Febiger, 1968;
3. Kremers and Urdang's, *History of Pharmacy*, 3rd Edition, 1963, Lippincott;
4. *The United States Pharmacopeias* for various years;
5. *Journal of the American Pharmaceutical Association* for various years;
6. *The Red Book, Blue Book and Pink Sheets* for various years;
7. *The American Professional Pharmacist*; and
8. *The American Druggist* for various years.

The Vanderschmidt Study, which lends support to my personal research and investigation (Appendix 9), was secured and distributed by an independent pharmacy consultant of high credentials. The questionnaire was processed anonymously; safeguards were employed to exclude any biases as set forth in your letter to me of May 5th. None of the responders knew or had any information of the parties involved, the purpose of the study, nor the injuries of your clients. I believe that the study was scientifically designed with data adequately secured and interpreted. Dr. Vanderschmidt's conclusions are:

Aaron M. Levine, Esq.

Page Six

October 12, 2004

- 1) The Survey is trustworthy and based on a well grounded sampling, considering the passage of time from the event we are considering.
- 2) Hearsay and memory risks were satisfactorily minimized.
- 3) The numbers of adequate responders was properly surveyed to obtain a representative sample.
- 4) The Questionnaire contained clear, precise and non-leading questions which were answered appropriately consistent with the sources of information.
- 5) The responders had no knowledge of the litigation nor could they have been influenced or sympathetic to any individual or company.
- 6) The mailings, returns and collating were protected, as well as the security and impartiality of the survey.
- 7) Statistical analysis was in accordance with accepted and standard epidemiological procedures.
- 8) Neither you nor anyone else engaged in such litigation nor any of the claimants have played any role in the design or conduct of this survey nor my conclusions.

#### Conclusions:

Based on my review of the literature, my experience, my discussions with other pharmacists and all the research and the investigation set forth above, it is my opinion to a reasonable degree of pharmaceutical and statistical certainty that Dr. Vanderschmidt's conclusion that Lilly's share of the DES market, in the pregnancy sizes, was 90% is conservative. From my standpoint, I would conclude that the following proportions are a more precise exact and realistic share of the market, as follows:

1. Lilly - 94%;
2. Squibb - 2%;
3. Assuming that the New York and California matrices are correct, Parke Davis, Brewer, Upjohn, Merck, Premo, and the other brands listed on these matrices, comprise the remaining 4% of the market.

Attached as Exhibit 19, is a listing of assorted synthetic estrogens or DES-like drugs on the market in the fifties and sixties. I understand there are some contentions made that DES

Aaron M. Levine, Esq.

Page Seven

October 12, 2004

(Diethylstilbestrol) was not the only or not the most popular synthetic estrogen in use for prevention of the accidents of pregnancy.

In all the research above, the hundreds of pharmacists and doctors with whom this topic has been discussed was never any mention to any of the products listed on exhibit 19, other than DES (Diethylstilbestrol) in the Commonwealth of Massachusetts. I am familiar with DES but experienced that Stilbestrol was the only synthetic estrogen product prescribed or dispensed.

Additionally, I am informed that a contention has been made that there may have been non-Lilly brands of DES which were white and cross-scored. I have reviewed the P.D.R., Red and Blue Books and volumes of photographs of DES products. From my experience, personal familiarity with these products, a review of the literature, I can state with absolute certainty that the only popular DES product which appeared round, white and cross-scored, about the size of an aspirin without any other imprint or logo, as in Exhibit 11, was the Lilly DES 25<sub>mg</sub> product.

I declare, under the penalty of perjury, that the foregoing statement is true and correct, based upon my personal knowledge of the facts set forth.

10/12/04  
Date

Harold B. Sparr  
Harold B. Sparr, R.P.H., M.S.

WITNESS:

Ant/C. Chke

# **APPENDIX 12**

October 22, 2003

\* Corrections/additions underlined.

### CORRECTED STATEMENT OF PHILIP J. CAFFERTY\*

I reside at 16 Triphammer Road, Hingham, MA 02043. I am 64 years of age and am a pharmacist and a former pharmaceutical representative of Eli Lilly and Co. I am familiar with the field of retail pharmacy inventory and stocking practices over the last 49 years in the Boston and Rhode Island areas, and the sales and marketing practices of Eli Lilly and Company for the last 49 years.

#### Career

1. I began my career in retail pharmacy in 1954 as a clerk and stock boy in a retail pharmacy in New England. Three years later, I began pharmacy school, but continued working in a retail pharmacy. From 1954, I have continuously been in the retail pharmacy industry as a clerk, pharmacist, detailman, or pharmaceutical district manager.

#### Licensing

2. I hold a degree in pharmacy from the University of Rhode Island and have been a licensed pharmacist since 1961, registered in the states of Massachusetts, Rhode Island and New York. I have been a member of the Massachusetts and Rhode Island Pharmacy Associations.

#### Scope

3. My employment in the field of pharmacy has given me the opportunity to be present at, observe, or converse with personnel in approximately 200 pharmacies in Massachusetts and Rhode Island over the last 49 years. In my experience over the last half century in dozens of drugstores, as a pharmacist, a pharmaceutical representative and detailman, both for Lilly and Miles Laboratory, I had the opportunity to review prescription forms, become familiar with drugs, drug popularity, as well as, physician prescribing habits. I have filled or reviewed drug prescriptions in the hundreds of thousands over the last 49 years. I am familiar with the practice of retail drugstores in the Boston and suburban retail pharmacies.

#### Lilly Employment

4. For 19 years commencing in 1965, I was employed by Eli Lilly and Company, Indianapolis, Indiana, as a professional representative or detailman and district manager. My duties included:

a. Calling on retail pharmacies to introduce new Lilly products, restocking shelves of the pharmacies with new inventory, maintaining inventory with proper shelf-life order, replacing outdated merchandise, credit for return. In this effort, I had responsibility for the stocking of Lilly products in approximately 200 pharmacies in Rhode Island and Massachusetts. In this position, I would have the

October 22, 2003

\* Corrections/additions underlined.

opportunity to cull through store prescriptions to observe physician prescribing habits.

b. Observing and originating reports regarding prescribing habits, frequency of prescription, popularity of prescription brands, drug indications, warnings, product presentation; and

c. Investigating physician's prescribing habits for both Lilly and competitors. Detailing physicians and pharmacists, which included observing shelf products for Lilly as well as for its competitors and speaking to doctors regarding their prescribing habits. Obstetricians and Gynecologists were some of the doctors I detailed.

#### Familiarity with the 1950s

5. I have actually filled over 14,000 prescriptions since 1957. Even though at first I was a pharmacy student under the supervision of a pharmacist, I had the opportunity to read prescriptions from physicians, fill, label, and dispense the medication in over 20 cities for over a half century. In addition, I commonly ordered pharmaceuticals from wholesalers and manufacturers. I also was familiar with pricing policy and coding. I averaged between 30 and 32 hours per week until 1961 when I graduated, became licensed and became engaged in full-time pharmacy practices. From then on, I was a full-time pharmacist.

#### Familiarity with DES

6. I am familiar with Diethylstilbestrol, also known as DES and Stilbestrol. I filled on the average of three or four prescriptions a week for DES starting in the late 1950s, but I have seen it on shelves in pharmacies since 1954. I knew it was indicated for prevention of miscarriage, among other uses, and I knew it came in different strengths from .1 mg to 25 mg. and in white uncoated tablets as well as red-coated pills. Diethylstilbestrol was the only popular oral hormone medication given in the 1950s and 1960s to pregnant women. It was the drug of choice and the standard treatment for pregnant women and the only popular oral medication regularly used for this purpose. I am familiar with the Lilly publication "De Re Medica" that was sent to the physicians of America, which advocates DES as the best medication for avoiding miscarriage.

#### Review of Literature

7. I have reviewed the commercial DES literature including PDR, Redbook, Bluebook, and U.S. Pharmacopoeia from the 1950s and 1960s. I have also reviewed Lilly publications in general from the 1950s and 1960s, such as field reference manuals, product labeling, inserts, product brochures, Tile and Till, The Lilly Digest and other Lilly publications regarding competitive pharmaceutical manufacturers. I was familiar with this material in the 1950s, 1960s and 1970s. From these readings as well as my observations of the practice of pharmacy, I observed what changes if any occurred in the

October 22, 2003

\* Corrections/additions underlined.

marketing, ordering, stocking and dispensing of retail pharmaceuticals over the last half century. The practices have remained relatively stable during the last half century.

## Lilly's Publications

8. I am familiar with Lilly's promotional publications in the 1950s, 1960s and 1970s especially De Re Medica, The Physician's Brochure, The Physician's Bulletin and other labeling. I recall detailing physicians in that period and observing these publications. I have seen them in drugstores, hospital pharmacies and doctor's offices.

## Survey of Pharmacists

9. I have reviewed over 105 sworn statements of other pharmacists regarding the prevalence and availability of the Eli Lilly DES products in their stores in the 1950s and 1960s. I have personally spoken with 17 pharmacists in the New England area who were practicing in the 1950s and 1960s as to their recollection of the DES market. Results of this research point to Lilly as the unique and unrivaled supplier.

## Lilly Products and Inventory

10. I recall the wholesaler strategy from the 1950s and 1960s by Eli Lilly and Company as well as their agreements with wholesalers throughout the country. Eli Lilly was the leading pharmaceutical manufacturer in America at that time with top market popularity because of its reputation, quality, control, efficiency of inventory and distribution through wholesalers. In the 1950s and 1960s Lilly was the only major pharmaceutical manufacturer from whom you could only order through a wholesaler and not directly from the company. Lilly was the only major drug house that employed licensed pharmacists as detailmen - this allowed them to have greater access to pharmacists and pharmacy stocking practices than any other company. Only the Lilly detailmen actually went behind the counter of a drugstore, pulled off outdated products and replenished the shelves. Lilly's practices enabled the retail pharmacists to save money. For example, DES was sold in eight forms: .1 mg, .5 mg, 5 mg and 25 mg both in coated and uncoated. This would require a pharmacist to invest in a minimum of eight bottles of 100 tablets. The pharmacist could receive a bottle at a time only from the Lilly wholesaler quickly, but for most of the other companies, ordering had to be done directly from the manufacturer, in larger orders, often taking a longer time requiring a greater investment in inventory at additional cost. Only Lilly, with its national network of Lilly wholesalers could allow a pharmacist to keep a single bottle of DES in one strength and color and get almost instant replenishment from the local wholesaler.

## Generics

11. Regarding generic manufacturers and generic substitution as it is known today, this is a phenomenon of recent years only. In the mid and late 1950s, generic companies and generic drugs were virtually unknown and unused. It was not until the late 1960s the generics began their popularity.

October 22, 2003

\* Corrections/additions underlined.

The Red and Blue Books do not Reflect the Market

12. I have reviewed the Red and Blue Books as well as the PDR for 1954 and 1958 as it applies to DES. Although the Red and Blue books may have listed many brands of DES available in the world, it is not an accurate presentation of the DES market in Massachusetts and Rhode Island during the 1950s and 1960s – the years of DES popularity. In all the pharmacies I have visited in Massachusetts and Rhode Island and of the hundreds of pharmacists I have talked to, I have never seen or heard of a DES product not manufactured by Eli Lilly. Perhaps some of the brands listed in the Red or Blue Books were dispensed in the South or on the West Coast, but not in Massachusetts or Rhode Island in any numbers. I have seen only Lilly's DES products in the drugstore of the Boston suburbs. If a doctor had specified a Squibb or Upjohn product, I am sure that the pharmacist would have had to fill the prescription that way, but if it were prescribed as merely DES, Stilbestrol or Diethylstilbestrol, it would have been filled with a Lilly product.

Continuity

13. I spent one year in the home offices of Eli Lilly in the creation of marketing plans and was a sales manager, having 12 detailmen under me, thus enabling me to observe, in addition to my other experiences, Lilly's pharmaceutical marketing and their manipulation of markets throughout America in distribution, sales practices, sales techniques and sales strategies. These strategies, customs and practices did not significantly change between the mid-1950s and late 1970s. The DES market in the mid-1950s remained the same through the 1960s.

Wholesaler Agreements

14. I have reviewed the Eli Lilly distributing and selling service agreement and Eli Lilly Warehousing and Distribution Service agreements. I have personal knowledge of their existence and workings over the last 45 years. Lilly entered into agreements with the following wholesalers in the New England area, with whom I am familiar: McKesson Robbins Company, the Gilman Brothers Company and the James W. Daly Cardinal Company. They were Lilly wholesalers and they controlled the Boston and Rhode Island pharmaceutical wholesaler distribution field. Under the agreement, these pharmaceutical wholesalers were obligated to provide a Lilly product "on all unspecified orders." The effect of this agreement was that if a local retail pharmacy ordered "DES," "Diethylstilbestrol" or "Stilbestrol" from these wholesalers, they would receive a Lilly product. The wholesaler was required to send a Lilly product or lose the Lilly account, which in those days was the biggest. I recall there were other brand name DES products. Squibb made a DES called Stilbetin and Upjohn made a DES called Perles, but these were trade names and had to be ordered that way by the physicians. Plain "DES" was always Lilly.

October 22, 2003

\* Corrections/additions underlined

Pill Description

15. The 25 mg. (pregnancy size) DES manufactured by Eli Lilly was a round white, cross-scored tablet without any other markings. It is pictured in the attached photograph. I am familiar with that drug having dispensed it on hundreds of occasions. No other manufacturers have such a DES product.

Conclusion

16. Based upon my observations of drugstores and familiarity with the pharmaceutical field, Lilly had the lion's share, if not all of the DES market. I observed no other brand of DES in stores in Boston and Rhode Island. Based on my experience and observations, it is inconceivable that I would not have seen or heard of a non-Lilly brand, had it been there.

I declare under penalty of perjury that the foregoing statement is true and correct and is based upon my personal knowledge of the facts set forth.

Date: 11/17/03

Philip J. Cafferty, R.Ph.  
Philip J. Cafferty, R.Ph.

Witness:

[Signature]

# **APPENDIX 13**

COPY

KAREN BERMAN and : COURT OF COMMON PLEAS  
JEFFREY BERMAN, w/h : PHILADELPHIA COUNTY  
VS : JANUARY TERM, 1993  
ABBOTT LABORATORIES et al: NO. 2244

---

DEBORAH NIERENBERG and : COURT OF COMMON PLEAS  
STEVEN NIERENBERG, w/h : PHILADELPHIA COUNTY  
VS : JANUARY TERM, 1993  
ABBOTT LABORATORIES et al: NO. 2958

---

Oral Deposition of LORNE V. PERSON,  
SR., Witness, on behalf of the Plaintiffs,  
pursuant to the Pennsylvania Rules of Civil  
Procedure, taken in the law offices of Sheller,  
Ludwig & Badey, Third Floor, 1528 Walnut Street,  
Philadelphia, Pennsylvania, on Friday, April 22,  
1994, commencing at or about 9:35 a.m., before  
Francine K. Guokas, C.R. - Commissioner.

---

FRANCINE K. GUOKAS  
COURT REPORTING  
6141 Woodland Avenue  
Phila., Penna. 19142

215-726-8855

LORNE V. PERSON, SR.

122

1 BY MS. KNISELY:

2 Q. When you say most is there someone  
3 who comes to your mind that you're aware of that  
4 would have knowledge of these things that is still  
5 alive other than the people you've already told us  
6 about?

7 A. No.

8 MS. KNISELY: I don't think I  
9 have any other questions.

10 MR. KWASS: No questions.

11 BY MR. CYR:

12 Q. I just want to ask you a few  
13 questions. Mr. Person, did Person and Covey ever  
14 sell DES other than to -- other than in the State  
15 of California and possibly the States of Arizona  
16 and Nevada did Person and Covey sell DES anywhere  
17 else in the United States?

18 A. I can state that pretty -- is it  
19 unequivocally or equivocally no.

20 Q. Mr. Person, did Person and Covey ever  
21 sell DES to wholesalers or distributors?

22 A. No.

23 Q. Did Person and Covey ever employ any  
24 agents, employees east of the Mississippi for the

LORNE V. PERSON, SR.

123

1 marketing or sale of DES?

2 A. No.

3 Q. And did Person and Covey ever sell,  
4 ship, or deliver any DES into any state east of  
5 the Mississippi including Pennsylvania, New  
6 Jersey, Delaware, New York?

7 A. No.

8 MR. CYR: Thank you.

9 BY MS. KNISELY:

10 Q. In response to your counsel's first  
11 question about selling other DES other than in  
12 Arizona, possibly Nevada, and California you said  
13 no.

14 Other than what we've already  
15 talked about today at this deposition do you have  
16 any other basis for that answer other than what  
17 we've already talked about today?

18 A. No.

19 Q. Do you have any other basis for any  
20 of the other answers you've given in response to  
21 your counsel's question other than what we've  
22 already talked about today?

23 MR. CYR: I'm just going to  
24 object to the form. Other basis? I mean

# **APPENDIX 14**

STATEMENT OF PHILIP MCGOVERN, M.D.

1. My name is Philip McGovern, M.D. I have been a licensed physician since graduating from New York Medical College in 1959.
2. I am a practicing OB-GYN with my offices presently located at 300 Mount Auburn Street, Suite 419 in Cambridge, Massachusetts.
3. My father, Philip McGovern, Sr., M.D., was also a licensed OB-GYN practicing in Cambridge, Massachusetts until his death in *Sept 1971*
4. I was familiar with his practice, and during the late 1960's and early 1970's, it was the standard of care to prescribe DES (diethylstilbestrol) to obstetrical patients who presented with the indications for its usage, i.e., a history of threatened abortion or prior miscarriage. It was my father's usual and customary practice to prescribe DES to pregnant women with these signs and symptoms.
5. It was also the practice and standard of care for any OB-GYN to be aware of the latest warnings, contraindications, and side effects for any drug prescribed to a patient.
6. The primary sources for awareness of the latest drug warnings, contraindications, and side effects include the Physicians' Desk Reference (PDR), manufacturers' product literature, and "Dear Doctor" letters. It was the standard of practice for any OB-GYN to read and heed these materials.
7. Had OB-GYN's been informed that DES carried any significant risk of permanent harm to the fetus, they would not have prescribed it to pregnant women or, at the very least, they would have advised the women of their risks.
8. I have no interest in the outcome of any DES claims at this time, and I give this statement based upon personal knowledge.

I declare under the penalty of perjury that the foregoing is true and correct.

*9/9/04*  
Date

*[Signature]*  
Witness

*Philip McGovern, M.D.*  
Philip McGovern, M.D.

# **APPENDIX 15**

# ELI LILLY AND COMPANY

## Warehousing and Distribution Service Agreement

\*

This Agreement, when executed by the Wholesaler's authorized representative and returned to, and executed by, Eli Lilly and Company (hereinafter called "Lilly") at Indianapolis, Indiana, will state the terms and conditions of the Wholesaler's agreement with Lilly for the period indicated herein.

### I. The Wholesaler Agrees:

#### A. Inventories.

1. To purchase from Lilly and maintain at all times a complete inventory of the Lilly Products listed in the Lilly Price List (such products hereinafter called separately and collectively "Products") sufficient to supply demand, and to resort to drop-shipment orders only when necessary because of conditions beyond the Wholesaler's control.
2. To maintain the Products under proper storage conditions, including such refrigeration as may be specified by Lilly.
3. To supply only Products that are not out-of-date, damaged, or shopworn.

B. **Sales Organization.** To maintain a sales organization, including outside salesmen, adequate for personal solicitation of orders for Products in Wholesaler's trading area.

C. **Sales Effort.** To promote the Products, to give them full selling efforts and full distribution services, and not to—

1. Refuse or fail to supply promptly the Products when specified, or
2. Give preference to any other brand of products when no brand is specified.

D. **Financial Statement.** To furnish Lilly upon request a copy of its annual financial statement or other evidence of its financial condition.

E. **Automatic Shipments.** To accept automatic shipment of Products in reasonable quantities.

F. **Payment for Products.** To pay in full all invoices for Products within sixty (60) days from the date thereof.

#### G. Compliance with Applicable Laws.

1. To comply fully with all federal, state, and local laws applicable to the purchase, handling, sale, or distribution of the Products, and
2. Not to sell any narcotics, barbiturates, or other Products to any person prohibited by any federal, state, or local law from acquiring or possessing such Products.

### II. Lilly Agrees:

A. **Shipment to Wholesaler.** To sell and ship Products (other than Products restricted to sale on a third-party basis) to the Wholesaler at the Net Wholesale prices shown in the Pricers' Edition of the Lilly Price List in effect on the date of shipment, such Net Wholesale prices being equal to the Suggested Net Trade prices specified in the Pricers' Edition of the Lilly Price List less the following discounts:

1. Group I Products—(marked "I" in the Pricers' Edition of the Lilly Price List): 16⅓ %
2. Group II Products—(marked "II" in the Pricers' Edition of the Lilly Price List): 20%

B. **Special Suggested Net Trade Prices.** To adjust the net wholesale prices on Products sold and shipped from the Wholesaler's inventory on transactions for which Lilly has recommended special suggested net trade prices. The adjustments shall be made in accordance with the procedure outlined in the Lilly Chargeback Manual. Chargebacks must be properly certified and submitted to Lilly at Indianapolis, Indiana, not later than the end of the month next following the month in which the sale is made by the Wholesaler. The adjustments will result in net wholesale prices which are equal to the recommended special suggested net trade prices less the following discounts:

1. **Sales at Special Suggested Net Trade Prices (e.g., from Quotations, Quantity Price Schedule, Purchase Agreements, etc.).**
  - a. Total value (of each item in the case of single items or of all items in an assortment) of less than \$50—  
Group I Products—16⅓ %  
Group II Products—20%
  - b. Total value (of each item in the case of single items or of all items in an assortment) of \$50 or more—10%

**2. Sales on Special Offers (Identified as Such by Lilly).****a. Special Offers with a total value of less than \$50—**

Group I Products—16⅔ %

Group II Products—20%

**b. Special Offers with a total value of \$50 or more—10%**

except that in no event shall the total annual dollar volume (at special suggested net trade prices) of sales to all Wholesalers on Special Offers providing Wholesalers a 10% discount exceed 10% of the dollar volume (at suggested net trade prices) of Lilly's total domestic sales to all Wholesalers during the previous calendar year.

(Note: "Total value" for the purpose of subparagraphs 1. and 2. of this Paragraph B. shall be calculated on the basis of the recommended special suggested net trade prices.)

**C. Shipment to Third Parties.** To sell the Products to the Wholesaler upon third-party orders with shipment direct to the customer (i.e., drop shipments) at the applicable suggested net trade prices, regular or special, less 10%.**D. Transportation.** To ship the Products F.O.B. Indianapolis, Indiana, transportation prepaid, subject to the following:**1. Transportation Selected by Lilly.** Lilly will prepay that portion of the transportation charges set forth below when routing is selected by Lilly.**a. Shipments to the Wholesaler:**

(1) Special Shipments. All shipments of (a) Products deferred from previous orders; (b) Products that are newly released for Wholesaler stocks (initial shipment and all reorders for first thirty [30] days after release date); and (c) allocated shipments: 100%

(2) Regular Shipments. Shipments, other than Special Shipments, covered by the first two orders each week marked "Transportation Prepaid" by the Wholesaler: 100%

(Note: The "first two orders each week" means the first and second orders marked "Transportation Prepaid" received by Lilly at Indianapolis, Indiana, from the Wholesaler during the period beginning at the close of business Friday and ending the following Friday at the close of business, determined on the basis of the date and time stamp placed on the order by Lilly at the time of receipt. An order for purposes of the foregoing shall include all Products in an order received by Lilly at one time and for prompt shipment, even though for the purpose of handling and shipping it is necessary for Lilly to divide it into components, e.g., biologicals, narcotics, etc.)

(3) All other shipments to the Wholesaler: None

**b. Shipments on Third-Party Orders:**

(1) Products not released for Wholesaler stocks: 100%

(2) All other Products: 50%

**2. Transportation Selected by Wholesaler.** If the Wholesaler requests special routing of a shipment which results in a higher transportation cost than would be incurred as a result of the routing of Lilly's selection, then the extra cost shall be added to the invoice.**3. Title and Risk of Loss.** Title and risk of loss shall pass to the Wholesaler when the Products are duly delivered to the carrier.**E. Return for Credit.** To receive from the Wholesaler for credit the Products purchased from Lilly, subject to the following:

1. All returns must be sent to Lilly at Indianapolis, Indiana, accompanied by a Merchandise Returned Form (60 DQ 9408), and must be approved by the Lilly salesman responsible for the Wholesaler, the District Manager, or other authorized representative of Lilly. Transportation for returns made upon request by Lilly shall be paid by Lilly. Transportation for all other returns shall be paid by the Wholesaler. Full credit will be allowed at the Net Wholesale prices in effect on the date of the return, except on Products damaged while in the Wholesaler's possession.

2. Undamaged Products in original containers may be returned, except biological Products prior to their date of expiration and Products marked "Nonreturnable." No credit will be allowed for parts of sales packages, in-date biological Products, or other unauthorized returns, and any that are returned will be destroyed.

3. Damaged Products for which a claim can be substantiated against a carrier may be returned when sent to Lilly at Indianapolis, Indiana, free astray via responsible carrier.

4. Products damaged in shipment, but for which claim cannot be substantiated against a carrier because the concealed damage was not discovered within the required period for inspection, may be returned, subject to inspection and approval by the Lilly salesman responsible for the Wholesaler. Return shipment is to be made apart from regular returned goods shipments.

5. Actual salvage value, if any, will be allowed on Products damaged while in the Wholesaler's possession except that no allowance will be made in case of damage by careless handling or from such perils as are normally insured under the standard fire insurance policy, including extended coverage, vandalism, and malicious mischief.

**III. General Provisions.****A. Orders for Products.**

1. All orders are subject to acceptance and approval by Lilly at Indianapolis, Indiana.
2. In the event of a shortage of any of the Products, Lilly shall have the right, in its sole discretion, to allocate such Products among its various wholesalers.
3. Lilly may, from time to time upon written notice to the Wholesaler, change the Group designation of any of the Products and may add or withdraw Products from any Lilly price list.
4. Lilly may, in its discretion, designate certain Products which will be supplied in shelf-carton or shipping-case quantities only.

**B. Billing and Payment.**

1. All orders for Products shall be invoiced as of the date shipped. Lilly may, at its option, grant extended dating on invoices covering initial distribution of selected new Products. Such extended dating, if granted, will be announced at the time of the initial shipment of the new Products.
2. Lilly shall render a monthly statement to the Wholesaler which will include all invoices and all credits issued by Lilly during the month. Subject to the provisions of Section III. B. 3., Lilly shall grant the Wholesaler 2 percent cash discount on the statement balance if remittances covering monthly statements in full, excluding extended dating invoices, are received by Lilly at Indianapolis, Indiana, on or before the fifteenth (15th) of the month immediately following the statement date. Otherwise, invoices shall be due net sixty (60) days from date of invoice.
3. Lilly may require that each order from the Wholesaler be accompanied by a certified check or other payment satisfactory to Lilly in an amount sufficient to cover the order less a cash discount of 2 percent in the event (a) reasonable grounds for insecurity arise with respect to the performance by the Wholesaler under this Agreement or (b) Lilly has given notice of termination of this Agreement.
4. Products shipped but not paid for at the time of the cancellation or termination of this Agreement shall be paid for in accordance with the terms of this Agreement.

**C. Inspection of Inventory.** A Lilly representative will consult with and advise the Wholesaler concerning the Wholesaler's inventory of Products and may inspect the same at all reasonable times.

**D. No Exclusive Territory.** This Agreement does not grant the Wholesaler any exclusive rights in any territory.

**E. Buyer-Seller Relationship.** The relationship created by this Agreement is a buyer-seller relationship and not an agency relationship.

**F. Change in Ownership of or Controlling Interest in Wholesaler.** The Wholesaler shall give ten (10) days' prior notice of the sale or other transfer of substantially all the assets of or a controlling interest in the Wholesaler.

**G. Direct Sales.** Lilly reserves the right to sell directly to the U. S. Government, the American Red Cross, and manufacturers.

**H. Repurchase of Stock.** Upon cancellation or termination of this Agreement, by expiration or otherwise, Lilly shall have the option to repurchase the Wholesaler's salable stock of Products at the Net Wholesale prices then in effect.

**I. Assignment.** Neither party shall assign its rights or obligations under this Agreement without first obtaining the written consent of the other party, and any attempted assignment without such written consent shall be void and of no effect.

**J. Contingencies Affecting Performance.** Neither party shall be liable for delay in performance or nonperformance caused by fire, flood, storm, earthquake, or other act of God, war, rebellion, riot, failure of carriers to furnish transportation, strikes, lockouts or other labor disturbances, act of governmental authority, inability to obtain material or equipment, or any other cause of like or different nature beyond the control of such party.

**K. Notices.** All notices under this Agreement shall be in writing and shall be considered given when delivered or mailed postage prepaid by registered or certified mail to the address of the party to whom notice is given as set forth on the next page.

**L. Termination or Cancellation.**

1. This Agreement shall terminate on June 30, 1971, unless renewed or sooner terminated as herein provided.
2. During its term this Agreement may be terminated by either party upon thirty (30) days' notice.
3. This Agreement shall terminate at the time substantially all the assets of or a controlling interest in the Wholesaler is sold or otherwise transferred to a new owner.
4. Either party may cancel this Agreement upon notice for breach by the other party of any covenant contained herein.

- M. **Renewal.** At the option of Lilly and the Wholesaler, this Agreement may be renewed for successive terms of one (1) year. If the Wholesaler desires to renew, it shall send to Lilly at Indianapolis, Indiana, a written request for renewal forms before April 30. Duplicate copies of the renewal form executed by the Wholesaler shall be delivered or mailed to Lilly at Indianapolis, Indiana, not less than thirty (30) days before the expiration of any current term. If Lilly agrees to the renewal, it shall execute each renewal form and return one executed form to the Wholesaler.
- N. **Entire Agreement.** This Agreement shall (1) supersede all prior contracts, agreements, and understandings between the Wholesaler and Lilly, all of which are hereby terminated, except any unexpired agency agreements between Lilly and the Wholesaler under U. S. Government contracts; (2) constitute the complete agreement of the parties; and (3) be controlling to the exclusion of all terms and conditions of the Wholesaler's purchase orders or other documents in conflict with this Agreement.
- O. **Governing Law.** This Agreement shall be interpreted in accordance with, and governed by, the laws of the State of Indiana.

IN WITNESS WHEREOF, the Wholesaler has executed this Agreement and the same has become finally effective on the.....first.....day of.....July.....1970....., upon execution at Indianapolis, Indiana, by an authorized representative of Lilly.

**WHOLESALER:**

.....  
(NAME)

.....  
(STREET)

.....  
(CITY) (STATE) (ZIP CODE)

.....  
(\*ESTABLISHMENT REGISTRATION NUMBER)

By.....  
(SIGNATURE)

.....  
(TITLE)

**LILLY:**

**ELI LILLY AND COMPANY**  
307 East McCarty Street  
Indianapolis, Indiana 46225

By.....  
(VICE-PRESIDENT)

\*Number assigned by the Food and Drug Administration to the facility covered by this Agreement.

# **APPENDIX 16**

63

# COLOR ADDITIVES

MAR 18 1961

000487

## HEARINGS

BEFORE THE

## COMMITTEE ON

## INTERSTATE AND FOREIGN COMMERCE

## HOUSE OF REPRESENTATIVES

EIGHTY-SIXTH CONGRESS

SECOND SESSION

ON

H.R. 7624

A BILL TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT SO AS TO AUTHORIZE THE USE OF SUITABLE COLOR ADDITIVES IN OR ON FOODS, DRUGS, AND COSMETICS, IN ACCORDANCE WITH REGULATIONS PRESCRIBING THE CONDITIONS (INCLUDING MAXIMUM TOLERANCES) UNDER WHICH SUCH ADDITIVES MAY BE SAFELY USED

S. 2497

AN ACT TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT SO AS TO AUTHORIZE THE USE OF SUITABLE COLOR ADDITIVES IN OR ON FOODS, DRUGS, AND COSMETICS, IN ACCORDANCE WITH REGULATIONS PRESCRIBING THE CONDITIONS (INCLUDING MAXIMUM TOLERANCES) UNDER WHICH SUCH ADDITIVES MAY BE SAFELY USED

JANUARY 26, 27, 29, FEBRUARY 10, 11, MARCH 11,  
APRIL 5, 6, AND MAY 9, 1960

Printed for the use of the Committee on Interstate and Foreign Commerce

UNITED STATES  
GOVERNMENT PRINTING OFFICE  
WASHINGTON : 1960

34127

MAR 18 1981

000500 76

## COLOR ADDITIVES

265

Congressman, I understand you have a very distinguished constituent with you and we would be very happy to have you introduce him.

Mr. Bazz. Mr. Chairman and gentlemen, I do indeed have a most distinguished constituent of mine with me today, Dr. Thomas P. Carney, who is the vice president of research and development control of the Eli Lilly & Co. at Indianapolis. I would like to tell you just a little bit about Dr. Carney before he starts his testimony.

Dr. Carney is a graduate of Notre Dame, chemical engineering; had his Ph. D. at Penn State. He took his postdoctorate work at the University of Wisconsin.

Dr. Carney has been a past chairman of the Medical Division of the American Chemical Society. He has been a chairman of the agents committee advisory to chemical warfare; he is a former chairman and a present member of the industry subcommittee, the National Chemotherapy Service Center. Dr. Carney has been associated with Eli Lilly & Co. about 15 years.

I wanted to tell you just a little bit about the Eli Lilly & Co. I am not here on behalf of the drug industry, but I can tell you about one pharmaceutical manufacturer that is resident in my constituency. The Eli Lilly & Co. is an old, old company. It is a pioneer in research in the United States of America, one of the first industrial organizations in this country ever to seriously attempt research.

Dr. Carney, here, today, is in the long historical flow of research of that company. It actually started, their research efforts started, back in about 1900 under the direction of Dr. G. H. A. Clowes, who, incidentally, was one of the first men in the world, literally in the world, to attempt cancer research. He brought the first cancerous tissue from England in 1903 to this country. That tissue, incidentally, is still growing in the laboratories of the Eli Lilly & Co.

Men such as Mr. G. B. Walden, who helped pioneer insulin for pernicious anemia; men such as Dr. Horace Schoute, who worked in developing barbituric acid, men who work with Dr. Carney today and in whose footsteps he has followed; Dr. Carney, I can assure you, is not only a distinguished member of my constituency but a great American scientist in what I believe to be the best tradition.

I am delighted to present him to you gentlemen of this committee. Thank you.

STATEMENT OF DR. THOMAS CARNEY, VICE PRESIDENT, ELI LILLY & CO.

Dr. CARNEY. Thank you very much, Congressman.

Gentlemen and members of the committee, I want to express my gratitude to you and that of the pharmaceutical industry and of my State. I want to express our appreciation to you for allowing me to present our point of view today.

I appear before the committee as chairman of the Committee for the Study of Carcinogenic Substances of the Pharmaceutical Manufacturers Association to present a statement on behalf of the association.

This statement will be confined to a discussion of the implications of the so-called cancer clause, or Delaney amendment (sec. 706(b)(5)

000512

88

MAR 18 1991

COLOR ADDITIVES

277

The CHAIRMAN: Mr. Mack.

Mr. Mack. Doctor, is stilbestrol produced by most of the manufacturers, pharmaceutical manufacturers?

Dr. CARNEY. ~~No. Stilbestrol is produced only by three companies in this country.~~ Stilbestrol can be produced by anybody. It is an open compound.

Mr. Mack. It is only produced by three manufacturers?

Dr. CARNEY. Yes. As nearly as I know, three manufacturers; yes, sir.

Mr. Mack. You indicated it was very important in the production of beef animals?

Dr. CARNEY. Yes. About 75 percent of all of the beef animals in feedlots are on stilbestrol. Perhaps I should amplify my first statement and say what I mean by production. I meant production of the crude chemical. There are hundreds of feed manufacturers selling stilbestrol to the farmer. Possibly I misunderstood what you meant. I meant the actual production of the crude chemical stilbestrol, which then goes into feed which is sold to the feed manufacturers, the feed mixers.

Mr. Mack. Are there any other chemicals used in the feeds similar to stilbestrol?

Dr. CARNEY. There is one other product, hormone, which is used by implantation in beef cattle; but that is the only other hormone with which I am familiar.

Mr. Mack. Are there any other chemicals that fall into the same category as stilbestrol?

Dr. CARNEY. By "category," do you mean use, sir, or activity? There are other chemicals that are used for increasing the weights of the animals. I think the fact that 75 percent of the animals in this country are on one product indicates that it is rather an unusual material.

Mr. Mack. Then would this Delaney amendment affect many other chemicals other than stilbestrol?

Dr. CARNEY. It would not affect any of the chemicals that I know of that are used in this field. You see, the two primary materials under the Delaney amendment now are the arsenic compounds and stilbestrol, which was mentioned specifically.

Mr. Mack. So stilbestrol is about the only one that really would be affected?

Dr. CARNEY. As far as the Delaney amendment is concerned now; yes, that is right.

Mr. Mack. That is all, Mr. Chairman.

The CHAIRMAN: Mr. Younger.

Mr. YOUNGER. Just a comment. I do want to congratulate Dr. Carney on a presentation of the subject which a layman can understand.

Dr. CARNEY. Thank you, sir.

Mr. YOUNGER. Thank you. That is all.

The CHAIRMAN: Mr. Roberts.

Mr. ROBERTS. Mr. Chairman, I would like to join the chairman in saying that I think this is a very informative statement. It is one that is very hard for me to use as the basis for questions. I am certainly not a chemist and Dr. Carney is certainly a great chemist.

COLOR ADDITIVES

000518

283

94

principles of the Delaney amendment will apply to your field of industry.

Dr. CARNEY. Yes. They can exercise their scientific judgment and say these are dangerous. The results might be the same, incidentally. I am not saying that they would not necessarily be the same, but the conclusion would be based on scientific judgment and not on a law that says we cannot use these things. If it is proven that these compounds we have coming out are carcinogens, if it is proven they are dangerous, then Food and Drug can keep them off the market without a Delaney amendment at all.

Mr. Moss. ~~What percentage of the population of consumers is in the~~

~~What percentage of the population is in the~~

Dr. CARNEY. I would have—I do not have the exact figures, but I would say well over half.

Mr. Moss. Half.

Dr. CARNEY. ~~It is about 50 percent.~~

Mr. DINGELL. And the bulk of it goes into animals?

Dr. CARNEY. The bulk of it goes into animals.

Mr. DINGELL. Principally cattle?

Dr. CARNEY. Principally cattle, and sheep have been approved for use.

Mr. Moss. That is all I have.

The CHAIRMAN. Mr. Nelsen.

Mr. NELSEN. I wish to thank the gentleman for his very fine testimony, and I would like to point out, in the livestock feedings as well as poultry, that I think it would be unfair for us to assume that everything that has been suggested might lead to some defect in the meat product.

For example, in poultry if those of us who live on a farm—and that is where I make my bread and butter—you can take poultry and crowd them and get them to the market in a very short period of time; you will find perhaps that the quality of the bird is not as good and as tasty as one that has been given a wee bit more time, and the same is true of beef. So the quality of beef could be attributed to many factors, and this could be one, sure, but it is not necessarily true it is.

Mr. Moss. If the gentleman will yield, the gentleman is apparently addressing his remark at me rather than Dr. Carney.

First, let me disclaim any connection with a farm as an operator. I do not live on one, I do not operate one, and, therefore, I feel that I am completely free of any of the special pressures which might crowd my judgment. I tried to review this objectively. My statement was that I had been told by those whom I regard as expert that their view of this matter was different from Dr. Carney's. I did not indicate whether or not I agree with them. I merely brought it out because the doctor had stated here, rather strongly, conclusions which would leave one to believe in some instances that there was no area of disagreement, and I wanted to illustrate very clearly that there are substantial areas of disagreement, that the conclusions of the doctor are his best judgment, but equally well informed men have strong convictions the other way.

Dr. CARNEY. Incidentally, the conclusions on the carcass quality of the meat are backed up by assays run on 22 of the land-grant colleges in the country who are reasonably objective in this type of thing.

# **APPENDIX 17**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

NICOLE LEE DUNSETH,

Plaintiff,

v.

ELI LILLY AND COMPANY,

Defendant.

Civil Action No. 03-CV-02123 (RBW)

MEMORANDUM OPINION

Currently before the Court is Defendant Eli Lilly and Company's Motion for Summary Judgment [D.E.# 13] ("Def.'s Mot."). The defendant argues in its motion that this Court should grant summary judgment in its favor because the plaintiff, Nicole Lee Dunseth, has not and cannot produce evidence to identify Eli Lilly and Company ("Eli Lilly") as the manufacturer of the drug that allegedly caused her harm. Def.'s Mot. at 1. For the reasons set forth below, the defendants' motion will be denied.

**I. Background**

The plaintiff initially filed a five-count complaint in the Superior Court of the District of Columbia and the case was subsequently removed to this Court on October 17, 2003. See Notice of Removal. The plaintiff alleges that she suffered injuries as a result of "embryonic exposure" to DES. Compl. ¶ 4. According to the plaintiff, her mother was prescribed and took DES while pregnant with the plaintiff in 1969. Id. ¶ 3. The Plaintiff alleges that the DES her mother ingested, the same DES which allegedly caused her injuries, was manufactured by the defendant. Id. ¶¶ 3-5. The defendant argues that the plaintiff has failed to prove that it was the defendant's

product that caused her harm. Defendant Eli Lilly and Company's Memorandum of Points and Authorities in Support of its Motion for Summary Judgment ("Def.'s Mem.") at 1. The defendant asserts that the plaintiff has provided no medical or pharmacy records indicating that the defendant produced the DES in question here. Id. The defendant also contends that at least sixty other manufacturers produced the same drug that allegedly caused the plaintiff's injuries. Id. The defendant argues that the description provided by the plaintiff's mother of a small, white pill with a cross score on it fails to distinguish a DES pill made by the defendant from other DES products whose physical appearance fits the same description. Id. The defendant further argues that even if one of the defendant's products, in some dosage, matches the description given by the plaintiff's mother, it would be impermissible to allow a jury to find for the plaintiff. Id. at 2. Thus, the defendant contends that the plaintiff's claims fail as a matter of law if she cannot identify the brand of DES her mother ingested while pregnant to the exclusion of other DES products on the market at that time. Id.

## II. Summary Judgment Standard

This Court may grant a motion for summary judgment under Rule 56(c) "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." Fed. R. Civ. P. 56 (c). A genuine issue of material fact exists if "a reasonable jury could return a verdict for the nonmoving party." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "Credibility determinations, the weighing of the evidence, and the drawing of legitimate inferences from the facts are jury functions, not those of a judge . . . ." Id. at 255. The entry of summary judgment is appropriate after there has been an

"adequate time for discovery . . . [and the] party [against whom the motion has been filed] fails to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986).

Summary judgment, however, "is a drastic remedy, [and therefore] courts should grant it with caution so that no person will be deprived of his or her day in court to prove a disputed material factual issue." Greenberg v. Food & Drug Admin., 803 F.2d 1213, 1216 (D.C. Cir. 1986). Summary judgment is, accordingly, not appropriate where "the evidence presented on a dispositive issue is subject to conflicting interpretations, or reasonable persons might differ as to its significance . . . ." Id. (citations omitted). Moreover, when reviewing the evidence, the Court must draw "all inferences . . . in favor of the nonmoving party[.]" Coward v. ADT Sec. Sys., Inc., 194 F.3d 155, 158 (D.C. Cir. 1999); Aka v. Wash. Hosp. Ctr., 156 F.3d 1284, 1295 (D.C. Cir. 1998). The party opposing a motion for summary judgment, however, "may not rest upon the mere allegations or denials of his pleading, but . . . must set forth specific facts showing that there is a genuine issue for trial." Anderson, 477 U.S. at 248. And, the non-moving party "must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586 (1986). Moreover, "any factual assertions in the movant's affidavits will be accepted . . . as being true unless [the opposing party] submits [her] own affidavits or other documentary evidence contradicting the assertion." Neal v. Kelly, 963 F.2d 453, 456 (D.C. Cir. 1992) (quoting Lewis v. Faulkner, 689 F.2d 100, 102 (7th Cir. 1982)).

The mere existence of a factual dispute by itself, however, is not enough to bar summary

judgment. Rather, the party opposing the motion must show that there is a genuine issue of material fact. See Anderson, 477 U.S. at 247-48. To be material, the fact must be capable of affecting the outcome of the litigation; to be genuine, the issue must be supported by admissible evidence sufficient for a reasonable trier of fact to find in favor of the nonmoving party. Id.; see also Laningham v. United States Navy, 813 F.2d 1236, 1242-43 (D.C. Cir. 1987).

### III. Analysis

#### A. Choice of Law

As an initial matter, the defendant contends that the "substantive law of Illinois governs [the] plaintiff's claims." Def.'s Mem. at 5. The plaintiff does not appear to necessarily contest the application of Illinois law, stating that she "does not dispute that under Illinois, Nevada, and District of Columbia law, [the plaintiff] must identify the DES maker in question." Plaintiff Nicole Lee Dunseth's Memorandum of Points and Authorities in Support of her Opposition to Defendant's Motion for Summary Judgment ("Pl.'s Opp'n") at 12. However, because the plaintiff indicates that the laws of Nevada and District of Columbia may also apply, the Court must assess which state's laws applies in this case. In resolving this question, the Court must perform a "governmental interests" analysis. Herbert v. District of Columbia, 808 A.2d 776, 779 (D.C. 2002). As part of this analysis, the Court will consider the four factors set forth in the Restatement (Second) of Conflict of Laws (1971) § 145, Comment d, as has the District of Columbia Court of Appeals. These factors are: (a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (d) the place where the relationship is centered. Herbert, 808 A.2d at 779 (citations omitted).

As to the first factor – the place where the injury allegedly occurred – the plaintiff's mother was prescribed, bought, and ingested the DES that allegedly caused the plaintiff's injuries while living in Illinois. The plaintiff was also born in Illinois. There is no evidence that the plaintiff's mother lived in the District of Columbia while she was taking DES, nor is there any evidence that the plaintiff's mother, or the plaintiff, ever lived in the District of Columbia. Consequently, any injury suffered by the plaintiff did not occur in the District of Columbia. An analysis of this factor does not favor applying District of Columbia law, and therefore, because the injury occurred in Illinois, the first factor favors applying the law of Illinois.

The second Restatement factor – the place where the conduct causing the injury allegedly occurred – also does not favor applying District of Columbia law. The plaintiff alleges that “the [d]efendant met with and conspired with numerous pharmaceutical manufactures in the District of Columbia, prior to obtaining governmental approval for DES.” Compl. ¶ 2. Additionally, the plaintiff contends that the “[d]efendant spearheaded industry-wide conferences in the District of Columbia to seek approval of DES by Joint Submission, withholding from the Food and Drug Administration (“FDA”) reports questioning the efficacy of DES and studies raising serious questions of safety.” Id. The plaintiff asserts that these meetings, conferences, and agreements occurred in the District of Columbia. Id. The defendant admits that it has sold and distributed its product in the District of Columbia and that the FDA, which is located in the District of Columbia, approved the sale of the product. See Answer ¶ 2. And, while the defendant has admitted that it sold DES in the District of Columbia, it notes that there is no evidence that the DES bought or ingested by the plaintiff's mother ever passed through the District of Columbia. Def.'s Mem. at 5. As such, although the defendant has some affiliation with the District of

Columbia, this second factor nonetheless does not favor applying District of Columbia law because the place where the location of the conduct that purportedly caused the injury is Illinois. Accordingly, the second Restatement factor also favors the application of Illinois law.

The third factor for the Court to consider under the Restatement is the domicile, residence, nationality, place of incorporation and place of business of the parties. The plaintiff is currently domiciled in Nevada, see Notice of Removal ¶ 2 and the defendant is incorporated in Indiana with its principle place of business in Indianapolis, Indiana. Id. Because neither party is domiciled in, resides in, is incorporated in, or has a principle place of business in the District of Columbia, this third factor also does not favor applying District of Columbia law. Neither does this factor support the application of Illinois law. However, residency and place of business are not dispositive in this choice of laws analysis because they are the only factors that do not favor applying Illinois law, while the other factors of the government interests analysis do. See Herbert, 808 A.2d 780. Moreover, "when the policy of one state would be advanced by application of its law, and that of another state would not be advanced by application of its law, a false conflict appears and the law of the interested state prevails." Id. at 779 (citation omitted). Thus, this Court concludes that because the injury allegedly occurred in Illinois, the conduct causing the injury allegedly occurred in Illinois, and, as discussed immediately below, the relationship of the parties was clearly centered in Illinois, the state of Illinois has the strongest policy interest in this matter.

The fourth Restatement factor also favors applying Illinois law because the relationship between the parties was clearly centered in Illinois. In Lakie v. Smithkline Beecham, 965 F. Supp. 49, 59 (D.D.C. 1997), also a products liability case, a former member of this Court found

that Virginia law applied there because the plaintiff purchased and used the product in question in Virginia. The court noted that "a state's interest in the application of its law is strongest when both the place of the injury and the domicile of the plaintiff are within its territory." *Id.* (citations omitted). While the plaintiff here is currently domiciled in Nevada, Illinois is the state where the plaintiff's mother was prescribed, bought, and ingested the DES that allegedly caused the plaintiff's injuries. Compl. ¶ 3. These facts, as well as the fact that the plaintiff was born in Illinois, *id.*, weigh heavily in the Court's decision here. Moreover, as noted already, the plaintiff does not appear to contest the application of Illinois law. Pl.'s Opp'n at 12. Consequently, based on the four Restatement factors, the Court concludes that Illinois law is the law that should govern the resolution of this matter.

**B. Is there a Genuine Issue of Material Fact as to Whether the Plaintiff can Identify Defendant as the Manufacturer of the DES that Allegedly Caused Her Injury?**

The defendant's summary judgment motion raises the question of whether, under Illinois law, the plaintiff can sufficiently identify the defendant's DES as the product that caused her injuries. Under Illinois law, a plaintiff has the burden of proving "that the defendant produced, manufactured, sold, or was in some way responsible for the product." Meshes v. Warren & Sweat Mfg. Co., No. 98 C 50064, 2001 WL 1002410 at \*3 (N.D. Ill. 2001) (quoting Smith v. Eli Lilly & Co., 560 N.E.2d 324, 328 (Ill. 1990) (citations omitted)). To prevail under the theories of either strict liability or negligence, "the plaintiff must establish some causal relationship between the defendant and the injury-producing agent." Smith, 560 N.E.2d at 328. Proof of this causal relationship "may come in the form of direct or circumstantial evidence, but mere speculation, guess, or conjecture is not enough." Meshes, 2001 WL 1002410 at \*3 (citing Smith, 560 N.E.2d

at 328; Sutton v. Wash. Rubber Parts & Supply Co., 530 N.E.2d 1055, 1097 (1988)). “[W]here circumstantial evidence is relied upon, the circumstances must justify an inference of probability as distinguished from mere possibility.” Zimmer v. Celotex Corp., 549 N.E.2d 881, 883 (Ill. App. Ct. 1989).

The Court finds that the description of the DES pills ingested by the plaintiff’s mother, coupled with the affidavit of Eugene L. Belczak, create “an inference of probability” that the DES in question here was manufactured by the defendant. Id. The plaintiff’s mother testified during her deposition that the Diethylstilbestrol (a type of DES) she ingested was “a small white pill that had a cross on it, not very big, no writing on it or anything like that. It just had a, it was marked with a cross.” Pl.’s Opp’n, Appendix (“App.”) 2 (June 7, 2004 Deposition of Diana Barrett (“Barrett Dep.”)) at 19-20. The plaintiff’s mother further testified that she was able to remember these details “because it was a very significant time in my life. I mean, I was afraid of having a miscarriage. So when I was taking that pill every day, it just is embedded in my mind. It was important, I was in the process of possibly losing my child. . . .” Id. at 61. While this description alone would not suffice to identify the defendant’s product, the plaintiff also submitted the sworn statement of Eugene L. Belczak, a pharmacist from the Chicago area. Mr. Belczak is a 1957 graduate of the University of Illinois School of Pharmacy. Pl.’s Opp’n, App. 6 (Statement of Eugene L. Belczak (“Belczak Stmt.”)) ¶¶ 1-2. Beginning in 1954 when he was an intern, Mr. Belczak worked continuously for forty years as a retail pharmacist in the Chicago area. Id. Mr. Belczak’s statement attests that he is familiar not only with the general pharmacy practices in the Chicago area, but specifically with “those pharmaceuticals commonly used for the care and treatment of pregnant women in the mid-to-late 1960’s in the greater Chicago area.”

Id. ¶ 5-6. Mr. Belczak unequivocally states that "[i]f a DES mother described a white, cross-scored tablet without any other markings or writing on it . . . , it had to be a Lilly product as no other brand of DES fitting that description was available in Southwest Chicago in 1969." Id. at ¶ 9. Given Mr. Belczak's statement and the plaintiff's mother's testimony, the Court finds that there is a genuine issue of material fact as to whether the plaintiff's mother ingested the defendant's DES. This finding precludes the Court from entering summary judgment for the defendant. See Anderson, 477 U.S. at 248.

Summary judgment is not appropriate where evidence "is subject to conflicting interpretations, or reasonable persons might differ as to its significance." Greenberg, 803 F.2d at 1216. Assuming the plaintiff's mother and Mr. Belczak will be called as witnesses at trial, it will be for the jury, as the trier of fact, to evaluate their credibility and the credibility of their statements. Id. The statements made by the plaintiff's mother and Mr. Belczak have shown there is more than simply some "metaphysical doubt as to the material facts." See Matsushita Elec. Co., 475 U.S. at 586. Here, the description of the DES given by the plaintiff's mother, when considered with the sworn statement of Mr. Belczak, create a genuine issue of material fact. This factual issue – whether or not the plaintiff has identified the defendant as the manufacturer of the DES in question – is material because it is capable of affecting the outcome of the litigation. See Anderson, 477 U.S. at 247-48; Laningham, 813 F.2d at 1242-43. The Court also finds that this factual dispute is genuine because it is supported by admissible evidence – the likely testimony of Mr. Belczak and the plaintiff's mother. See id. Accordingly, this Court cannot conclude from the evidence before it, that a reasonable juror could not find that the DES ingested by the plaintiff's mother was, in fact, manufactured by the defendant.

#### IV. Conclusion

The only issue before the Court at this time is whether the plaintiff has met her burden to sufficiently identify the defendant's product as the product used by her mother, that summary judgment would be inappropriate. Given the statement of Mr. Belczak and the plaintiff's mother's testimony, the Court finds that there is a genuine issue of material fact which precludes the Court from entering summary judgment for the defendant. Accordingly, the defendant's motion for summary judgment is denied.

SO ORDERED on this 16th day of September, 2005.<sup>1</sup>

REGGIE B. WALTON  
United States District Judge

---

<sup>1</sup>An Order consistent with this Memorandum Opinion is being issued contemporaneously herewith.

# **APPENDIX 18**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

CYNTHIA LEE GASSMANN,

Plaintiff,

v.

ELI LILLY AND COMPANY, et al.,

Defendants.

Civil Action 03-02592 (HHK)

MEMORANDUM OPINION AND ORDER

Plaintiff, Cynthia Lee Gassman, brings this products liability action against Eli Lilly and Company ("Eli Lilly") alleging she suffered injuries resulting from her embryonic exposure to Diethylstilbestrol ("DES"), a pharmaceutical produced and sold by Eli Lilly. Presently before the court is Eli Lilly's motion for summary judgment [#11]. Upon consideration of the motion, the opposition thereto, and the record of this case, the court concludes that the motion must be denied.

I. BACKGROUND

A. Factual History

DES is a synthetic estrogen that was developed and prescribed in the mid-twentieth century to prevent miscarriages and premature deliveries. An estimated five to ten million individuals in the United States were exposed to DES between 1938, the year it was first prescribed, and 1971, the year that the FDA advised physicians to stop prescribing it to pregnant

women because of its links to a rare vaginal cancer in female children.<sup>1</sup> According to the Center for Disease Control, medical research over the past thirty years has confirmed that women who were prescribed DES while pregnant have an increased risk of breast cancer and the women born of DES patients have increased risks of vaginal and cervical cancer, reproductive tract structural differences, pregnancy complications, and infertility. See CDC, ABOUT DES, <http://www.cdc.gov/des/consumers/about/index.html>.

In 1968, Gassman's mother, Lois Tholke, was prescribed DES by her treating obstetrician while she was pregnant with Gassman. Tholke remembers ingesting "a small white pill," but does not recall any other identifying characteristics of the DES pills she ingested or any information regarding the pills' manufacturer. At that time, DES was produced by over 75 companies, many of whom produced DES in the form of a small white pill. The current owner of the pharmacist where Tholke filled her prescriptions in 1968 stated that, although he did not own the store at the time, he personally observed that "the sole and exclusive brand of DES in the store was the Eli Lilly Brand, from the late 60s through the time I actually bought the store" in 1975. Pl.'s Opp'n, Exh. 25 ¶ 8.

On September 14, 1968, Gassman was born in Mineola, New York. In her early teens, she learned from her mother that she had been exposed to DES *in utero*. In October 1990, almost ten years after learning of her DES exposure, Gassman married her husband, Daniel Gassman. Less than a year later, Mr. Gassman was diagnosed with Hodgkin's disease, a cancer that starts in lymphatic tissue. As a result of this diagnosis, Mr. Gassman was required to undergo

---

<sup>1</sup> This estimate includes the women who were prescribed DES while pregnant as well as the female and male children born of these pregnancies.

chemotherapy treatments that would ultimately leave him sterile. Prior to the beginning of his treatment, Mr. Gassman had samples of his sperm frozen so that he and his wife could attempt artificial insemination at a later date.

Between July 1997 and June 1998, Gassman underwent three Intra-Uterine Inseminations with her husband's frozen sperm. Ultimately, none of the three inseminations resulted in pregnancy. Prior to these procedures, in May 1997, Gassman met with Dr. Serena Chen for an initial fertility consultation. Dr. Chen's notes from that consultation indicate that she "[r]eviewed with patients [the Gassmans] concerns about DES exposure, such as increased risk for poor pregnancy outcome, such as ectopic pregnancy, pre-term labor, cervical incompetence, etc." Def.'s Mot, Exh. 5. Gassman denies that she was told in any definitive manner that DES caused her infertility or even that she was infertile.

In or about June 1999, Dr. Chen told Gassman that she "had a T-shaped uterus from DES exposure." *Id.*, Exh. 3 ("Gassman Dep."), at 69. Dr. Chen's medical records from July 5, 1999, indicate that she "reviewed DES" and its "effect on fertility." *Id.*, Exh. 6. Gassman denies that Dr. Chen ever indicated that Gassman's T-shaped uterus or her DES exposure were related to her problems becoming pregnant. In fact, Gassman alleges that her doctors informed her that her chances of becoming pregnant using her husband's sperm were still good. She states that, at least until September 2000, she believed that her difficulties becoming pregnant were not a result of her *in utero* DES exposure, but rather were "due to [her husband's] chemotherapy." Pl.'s Opp'n, Exh. 20 ("Gassman Statement") ¶ 3.

Gassman claims that it was not until 2002, “at the earliest,” that she ever “had the slightest idea or suspicion that [her] injuries or infertility were caused by the wrongful conduct of the company that made the DES [her] mother took while pregnant with [her], or that anyone was suing over DES injuries, or that the manufacturer had done anything wrong.” *Id.* ¶ 4. Gassman indicates that she did not attempt to educate herself about the effects of DES “because there was nothing I knew to investigate. . . . I knew I was affected by DES, but there was still very positive a chance to become pregnant. There was nothing to investigate, it was a side effect of being born.” Gassman Dep. at 26. She also suggests that she did not investigate the possibility of a lawsuit because she “thought the company had tested the drug before they put it on the market,” and because she “believed the drug saved [her] life.” Gassman Statement ¶ 5. She states that she first learned about DES lawsuits in 2002. Prior to that date, she alleges that she never researched DES on the internet, never read legal or medical magazines about DES, never watched any television program about DES, never listened to any radio show about DES, and never joined any DES support group. *Id.* ¶¶ 6–10.

#### **B. Procedural History**

Gassman filed suit in D.C. Superior Court on February 19, 2003, naming five pharmaceutical companies—Eli Lilly, GlaxoSmithKline, Bristol-Myers Squibb Co. (“Bristol-Myers”), Pharmacia and Upjohn Company (“Pharmacia”), and Dart Industries Inc. (“Dart”)—as co-defendants. Her complaint alleges that Gassman suffered injuries including cervical and uterine malformations resulting in infertility as a result of her embryonic exposure to DES. She seeks compensatory and punitive damages against the pharmaceutical companies under theories of negligence, strict liability, breach of warranty, and misrepresentation.

Because both Gassman and Bristol-Myers were citizens of New York, the case as originally filed was not removable. On December 2, 2003, a Praecipe of Dismissal was filed in D.C. Superior Court, dismissing Bristol-Myers and Pharmacia with prejudice. Less than a week later, GlaxoSmithKline was also dismissed from the case. Soon thereafter, on December 19, 2003, Eli Lilly removed the case to federal court. Dart was eventually dismissed with prejudice on January 14, 2004, leaving Eli Lilly as the sole defendant.

Eli Lilly filed the present motion for summary judgment on December 1, 2004, arguing that all of Gassman's claims should be dismissed because they are barred by the applicable statute of limitations and because Gassman cannot identify Eli Lilly as the manufacturer of the drug at issue in this case.

## II. ANALYSIS

Under Rule 56 of the Federal Rules of Civil Procedure, summary judgment shall be granted if the pleadings, depositions, answers to interrogatories, admissions on file, and affidavits show that there is no genuine issue of material fact in dispute and that the moving party is entitled to judgment as a matter of law. Material facts are those "that might affect the outcome of the suit under the governing law." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In considering a motion for summary judgment, the "evidence of the non-movant is to be believed, and all justifiable inferences are to be drawn in his favor." *Id.* at 255. The non-moving party's opposition must consist of more than mere unsupported allegations or denials and must be supported by affidavits or other competent evidence setting forth specific facts showing that there is a genuine issue for trial. FED. R. CIV. P. 56(e); *Celotex Corp. v. Catrett*, 477 U.S. 317, 323–24

(1986). The non-moving party is “required to provide evidence that would permit a reasonable jury to find” in its favor. *Laningham v. United States Navy*, 813 F.2d 1236, 1242 (D.C. Cir. 1987). If the evidence is “merely colorable” or “not significantly probative,” summary judgment may be granted. *Anderson*, 477 U.S. at 249–50.

#### A. Statute of Limitations

Eli Lilly asserts that summary judgment is appropriate because Gassman’s claims are time-barred. Eli Lilly also asserts that New York statute of limitations, rather than District of Columbia law, may govern Gassman’s claims. Both the District of Columbia and the state of New York have a three-year statute of limitations applicable in cases like this one. *See* D.C. Code § 12-301(8); N.Y. C.P.L.R. 214(5). New York, however, offers plaintiffs an alternate limitations period if they are unable to learn the cause of their injury within three years of discovering it. In such cases, a plaintiff has five years from discovering her injury to determine its cause, and then one year from determining its cause to file suit. N.Y. C.P.L.R. 214-c(4); *Ruffing v. Union Carbide Corp.*, 746 N.Y.S.2d 798, 804–05 (N.Y. Sup. Ct. 2002). The District of Columbia applies a more fact-based discovery rule to determine when a cause of action accrues, discussed *infra*, which in many situations is more beneficial to plaintiffs.

##### 1. Choice of Law

Eli Lilly suggests that Gassman’s claims are time-barred under either the New York or District of Columbia statute, but suggests application of the New York statute is more appropriate. Def.’s Mot. at 16–18. To determine which jurisdiction’s laws should apply, the court must apply choice of law principles. Because the court’s subject matter jurisdiction in this

case is derived from the diversity of citizenship between the parties, the choice of law rules of the forum “state” are applied. *National Mut. Ins. Co. v. Richardson*, 270 F.3d 948, 953 (D.C. Cir. 2001); *Rogers v. Ingersoll-Rand Co.*, 144 F.3d 841, 843 (D.C. Cir. 1998). In the District of Columbia, the forum “state” here, limitations arguments have long been considered procedural, thereby mandating application of the filing forum’s statute of limitations. *Namerdy v. Generalcar*, 217 A.2d 109, 113 (D.C. 1966); *A.I. Trade Fin., Inc. v. Petra Int’l Banking Corp.*, 62 F.3d 1454, 1458 (D.C. Cir. 1995).

Eli Lilly seeks to have this court apply the revised Restatement (Second) of Conflicts of Law § 142 to this matter, under which statutes of limitations are treated as a matter of substantive law in certain instances. See RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 142 cmt. e (1998). Were the court to agree and consider Eli Lilly’s statute of limitations argument as a substantive matter rather than a procedural one, the court would be required to apply the law of the jurisdiction with the greatest interest in the litigation. *Greycoat Hanover F Street Ltd P’ship v. Liberty Mut. Ins. Co.*, 657 A.2d 764, 767–68 (D.C. 1995). The jurisdiction with the greatest interest, according to Eli Lilly, is New York.

Eli Lilly has made similar arguments before other courts in this jurisdiction. See, e.g., *Reeves v. Eli Lilly & Co.*, 368 F. Supp. 2d 11, 26–27 (D.D.C. 2005); *Epstein v. Eli Lilly & Co.*, Civ. No. 03-236, slip op. at \*4 (Sup. Ct. March 3, 2003). In rejecting Eli Lilly’s argument that a D.C. federal district court should adopt the revised Restatement, Judge Lamberth wrote:

While defendant asks this court to pioneer a path towards a more narrow choice of law analysis to the forum’s statute of limitations approach, that is not the role for this federal court. This court must faithfully apply the same law the District of Columbia courts would apply if this case were presently before them. This court takes “the law

of the appropriate jurisdiction as [found]; and we leave it undisturbed.” *Tidler v. Eli Lilly and Co.*, 851 F.2d 418, 425 (D.C. Cir. 1998). . . . The decision to approach a forum choice of law statute of limitation analysis as a substantive matter—applying a different forum’s statute of limitations time limit—is best left to the District of Columbia Court of Appeals.

*Reeves*, 368 F. Supp. 2d at 26–27. This court agrees with Judge Lamberth and concludes that, until the D.C. Court of Appeals instructs otherwise, statute of limitations analysis in the District of Columbia is to be treated as a procedural matter requiring reference to the filing forum’s applicable statute. As such, the District’s statute of limitations will apply to Gassman’s claims.

## 2. *The Discovery Rule*

Applying District of Columbia law, product liability claims must be filed within three years “from the time the right to maintain the action accrues.” D.C. Code § 12-301; *Smith v. Brown & Williamson Tobacco Corp.*, 3 F. Supp. 2d 1473, 1475 (D.D.C. 1998). In most cases, a cause of action will accrue at the time the injury actually occurs. *Mullin v. Washington Free Weekly*, 785 A.2d 296, 298 (D.C. 2001); *Diamond v. Davis*, 680 A.2d 364, 379 (D.C. 1996). However, in cases “where the relationship between the fact of injury and the alleged tortious conduct is obscure” when the injury occurs, a three-pronged “discovery rule” is applied to determine when the action accrues. *Diamond*, 680 A.2d at 379; *Williams v. Mordkofsky*, 901 F.2d 158, 162 (D.C. Cir. 1990). Under the discovery rule, a plaintiff’s claim does not accrue, and the statute of limitations does not begin to run, until the plaintiff know[s] (or by the exercise of reasonable diligence should know) (1) of the injury, (2) its cause in fact and (3) of some evidence

of wrongdoing.” *Bussineau v. President & Directors of Georgetown Coll.*, 518 A.2d 423, 425 (D.C. 1986).<sup>2</sup>

Importantly, when discussing what “quantum of knowledge is required to commence the running of the statute of limitations,” the D.C. Court of Appeals has made clear that both actual notice and inquiry notice will suffice. *Diamond*, 680 A.2d at 372 (“There are two types of notice: ‘actual notice’ is that notice which a plaintiff actually possesses; ‘inquiry notice’ is that notice which a plaintiff would have possessed after due investigation.”). A plaintiff is deemed to be on inquiry notice when, “if she had met her duty to act reasonably under the circumstances in investigating matters affecting her affairs, such an investigation, if conducted, would have led to actual notice.” *Id.* Whether a plaintiff has either actual or inquiry notice of his or her claim is a question of fact. *Id.*

Here, the parties agree that the discovery rule applies in this case, but dispute when Gassman “discovered” her cause of action, thereby starting the statutory clock. Eli Lilly argues that Gassman was placed on inquiry notice in 1999 when she “acknowledged her awareness of her reproductive injuries and their cause.” Def.’s Mot. at 11. At this point, according to Eli Lilly, Gassman was under an obligation to investigate whether her injuries were the result of some wrongdoing. *Id.* Eli Lilly also contends that, had Gassman “pursued reasonable avenues of investigation”—including researching medical literature, reading newspaper reports, searching

---

<sup>2</sup> The D.C. Court of Appeals has cited two considerations when holding that the third prong of the discovery rule—evidence of wrongdoing—must be present before a cause of action can accrue: (1) it would be inconsistent with notions of justice to allow a statute of limitations to begin to run before the plaintiff “would reasonably know of any wrongdoing,” *Diamond*, 680 A.2d at 379; and (2) an accrual rule that does not require the plaintiff to know of any wrongdoing “would encourage the filing of unfounded claims by plaintiffs seeking to protect their unknown rights.” *Id.*

the Internet, or speaking with her doctors—“there is no question that she could have, and would have, . . . learned about alleged wrongdoing by DES manufacturers.” *Id.* at 14.

Gassman responds by disputing that she was placed on inquiry notice in 1999 when she learned of her fertility problems and her T-shaped uterus. She begins by noting that fifteen percent of the population suffers from unexplained infertility, with many more suffering infertility as a result of endometrioses, dysmenorrhea, sexually transmitted diseases, and a host of other non-DES causes. Pl.’s Opp’n at 14. For this reason, Gassman argues that a problem pregnancy should not be “tantamount to notice of a lawsuit.” *Id.*

More specific to her particular situation, Gassman also denies that her doctors ever informed her that her problems becoming pregnant were caused by her *in utero* DES exposure, despite the fact that the notes from her medical record indicate that she was so informed. She states that she believed that the fertility issues were the result of her husband’s chemotherapy, not DES or her T-shaped uterus. To support this claim, Gassman asserts that her doctors were optimistic that, despite her T-shaped uterus, she could still become pregnant.

Gassman also asserts that, despite being aware that she was exposed to DES, she did not investigate Eli Lilly or other DES manufacturers because she trusted that pharmaceutical companies produced and sold safe drugs. She argues that “[t]here is not a single fact put forth by the Defendant that the doctors who treated [Gassman], her mother who took the drug, her friends, or anyone else in her milieu ever raised a hint suggesting wrongful conduct, failure to test, over promotion, negligence, failure to warn, failure to test or lawsuits, or even [that] DES causes infertility.” *Id.* at 16. She also introduces the declaration of the co-founder of a national, not-for-

profit consumer organization dedicated to informing the public about DES, who states that “DES exposed individuals generally do not relate their exposure to any wrongdoing.” *See* Affidavit of Patricia H. Cody, Pl.’s Opp’n, Exh. 7, ¶ 8 (“[DES exposed individuals] simply do not make the connection between their injury from a drug taken perhaps 35 to 40 years earlier by their mothers and wrongdoing by the drug’s manufacturer.”).

Further, Gassman asserts that, had she conducted an investigation into possible wrongdoing by DES manufacturers, reasonable avenues of investigation would not have placed her on actual notice of wrongdoing. To support this argument, she cites the fact that the overwhelming majority of articles discussing DES involved its effects on risks of cancer, not on fertility. She also argues that no DES manufacturer has ever admitted to liability or fault in any manner and that there is only one instance where a DES manufacturer settled a lawsuit without requiring an agreement of confidentiality from the plaintiff. Pl.’s Opp’n, Exh. 8. Gassman notes that, because of the asserted dearth of information about the ill effects of DES, the CDC, just this year, launched a comprehensive national program of DES education.

Ultimately, the court is left with a genuine dispute as to whether, in these circumstances, Gassman was, as a matter of law, on inquiry notice of her claim against Eli Lilly prior to February 19, 2000—three years before she filed her complaint in this case. As stated before, the issue of inquiry notice is a question of fact. At this stage of the proceedings, the court is *required* to believe the evidence of the non-movant and to draw all reasonable inferences in her favor. Doing so, the court must accept that Gassman was unaware of DES litigation prior to 2002, that she believed that her fertility was due to nothing other than her husband’s impotency, and that she never suspected that Eli Lilly was guilty of any wrongdoing. In these circumstances, the

court cannot find as a matter of law that Gassman was on inquiry notice of her claims against Eli Lilly such that her claims are time-barred. *Dawson v. Eli Lilly & Co.*, 543 F. Supp. 1330, 1335 (D.D.C. 1982) (Even when “strong inference might be drawn as to [the plaintiff’s] state of knowledge, such inferences should be left to the trier of fact.”); *Doe v. Medlantic Health Care Group, Inc.*, 814 A.2d 939, 946 (D.C. 2003) (“[S]ummary judgment is improper when there is a disputed question about plaintiff’s diligence in investigating a possible cause of action.”); *Braune v. Abbott Labs.*, 895 F. Supp. 530, 551 (E.D.N.Y. 1995) (“[T]he law does not build upon it to demand that ill people assume that every medical problem that they suffer resulted from the intervention of a malefactor. The public may reasonably assume the best rather than the worst

about the pharmaceutical industry.”).<sup>3</sup> Because there are genuine disputes as to material facts in this case, Eli Lilly is not entitled to summary judgment.<sup>4</sup>

## B. Identification of Manufacturer

Eli Lilly also argues that Gassman cannot identify Eli Lilly as the manufacturer of the DES to which she was allegedly exposed. Def.’s Mot. at 18–23. Under New York law, which governs the substantive matters in this case,<sup>5</sup> a plaintiff can seek relief under one of two different

---

<sup>3</sup> To support a contrary result, Eli Lilly cites two DES cases in which summary judgment was entered against the plaintiff on statute of limitations grounds: *Albers v. Eli Lilly & Co.*, 354 F.3d 644 (7th Cir. 2003), and *Roberge v. Eli Lilly & Co.*, 2005 U.S. Dist. LEXIS 3956 (D.D.C. Mar. 11, 2005). Eli Lilly’s reliance on these cases is misplaced. At the outset the court observes that neither opinion is binding on this court. More importantly, both cases are distinguishable, thereby undermining their persuasive reach.

The plaintiff in *Albers* stipulated that she was on actual notice of both her injuries and the cause in fact of those injuries for longer than the D.C. limitations period. *Albers*, 354 F.3d at 645. This fact prompted the court to conclude that a “reasonable person would have commenced an inquiry . . . and swiftly would have found some evidence of wrongdoing.” *Id.* Here, however, Gassman testified that she was unaware until at least 2002 that her DES exposure caused her injuries, believing instead that her husband’s chemotherapy was the culprit. Gassman Statement ¶ 4. The presence of this factual dispute is sufficient to distinguish *Albers*.

In *Roberge*, the plaintiff worked for an obstetrics and gynecology practice for many years, where she had “unfettered access to records documenting numerous cases of women with health problems resulting from DES exposure.” *Roberge v. Eli Lilly & Co.*, 393 F. Supp. 2d 49, 52 (D.D.C. 2005) (denying motion to alter judgment). From this important fact, the court concluded that there was “ample evidence in the record that plaintiff had continual access to resources that would have allowed her to investigate the possibility of filing a law suit based on DES exposure,” such that the plaintiff was held to be on inquiry notice of her claims. *Id.* Gassman, however, did not have such extensive access to medical information about DES and its effects on fertility. As such, this court cannot conclude that Gassman was, as a matter of law, on inquiry notice of her claims against Eli Lilly.

<sup>4</sup> To quote Judge Green in the oft-cited *Dawson* decision, “[o]f course, the factfinder may always conclude that plaintiff did or through the exercise of due diligence should have made that discovery sooner than the plaintiff claims was the case.” 543 F. Supp. at 1335.

<sup>5</sup> Eli Lilly contends that New York is the only forum with any conceivable interest in this litigation under District of Columbia choice of law principles, and therefore its substantive law applies here. See *Greycoat*, 657 A.2d at 767–68 (“Courts must apply the law of the forum with

theories of liability. The first—traditional product liability principles—requires that the plaintiff identify the specific product that actually caused the alleged injury in order for the plaintiff to meet his or her burden of proving causation. *Hymowitz v. Eli Lilly & Co.*, 539 N.E.2d 1069, 1073 (N.Y. 1989) (burden of proof on proximate causation lies with plaintiffs, which typically includes “identification of the exact defendant whose product injured the plaintiff.”).

Alternately, in response to the difficulty inherent in identifying the exact manufacturer of the DES ingested by a plaintiff’s mother many years prior to the lawsuit, the New York Court of Appeals allows DES plaintiffs to rely on market share liability, under which product identification is removed from the plaintiff’s causation burden in exchange for relegating plaintiff to a recovery equal to the named defendants’ share of the national DES market. *Id.* at 1078. In market share cases, unlike traditional product liability cases, some plaintiffs may be prevented from “recovering 100% of their damages.” *Id.*

Market share liability is the “default” causation standard in New York DES cases. *In re DES cases*, 789 F. Supp. 552, 564 (E.D.N.Y. 1992). However, a DES plaintiff who believes that she can meet the traditional market product identification burden is free to attempt to do so. *Id.*; *Hymowitz*, 539 N.E.2d at 1073 (“In DES cases in which [product] identification is possible, actions may proceed under established principles of product liability.”).

In this case, Gassman seeks recovery under traditional product liability principles and assert that Eli Lilly is the manufacturer of the DES that caused her injury. Eli Lilly argues that Gassman has not met her burden of proving “that it is reasonably probable, not merely possible

---

the more substantial interest in the litigation”). Gassman never disputes Eli Lilly’s assertion that New York substantive law governs.

or even balanced, that the defendant was the source of the offending product.” *Healey v. Firestone Tire & Rubber Co.*, 663 N.E.2d 901, 903 (N.Y. 1996). As such, Eli Lilly asserts that “no reasonable jury could find that Lilly’s pill was more likely than not the one that caused Plaintiff’s injuries,” thereby entitling it to summary judgment under the traditional product liability theories and forcing Gassman to rely on market share liability for any recovery to which she might be entitled. Def.’s Mot. at 20.

Gassman responds by arguing that she has “submitted ample product identification evidence to create a genuine issue of fact for jury submission.” Pl.’s Opp’n at 36. First, her mother testified that she took a “small white pill” to help sustain her pregnancy, a description that applies to the DES pill manufactured by Eli Lilly. Eli Lilly makes much of the fact that Gassman’s mother cannot remember any other identifying characteristics, including dosage or markings. Def.’s Mot. at 21. Because many DES manufacturers other than Eli Lilly produce a small white DES pill, Eli Lilly argues that Gassman fails to meet her burden of establishing causation. *Id.* at 22; *Healy*, 663 N.E.2d at 903 (granting summary judgment on product identification grounds where plaintiff’s description of a tire rim only narrowed the field of potential manufacturers to seven).

This argument would be more convincing had Gassman relied solely upon her mother’s memory of the shape and color of the DES pill she ingested to identify the product that allegedly injured her. Such is not the case. Gassman also notes that it is undisputed that the DES in this case was purchased at Phoster Pharmacy in Hempstead, New York. To establish that Phoster Pharmacy sold DES manufactured by Eli Lilly, and only Eli Lilly, during the relevant time period, Gassman introduces an affidavit of Herbert Mindlin, who purchased Phoster’s in 1975,

seven years after Gassman's birth. Mindlin testifies that he and the previous owner of Phoster's, Isaac Piel, were close friends. He claims that, beginning in 1968, he visited Piel at the pharmacy on numerous occasions. During these visits, Mindlin assertedly "had the opportunity to observe [Piel's] store, his practice, and the manner and method of the stocking of drugs in general and DES in particular, from the time of the late 60s until [Mindlin] actually bought [Piel's] store in 1975." Pl.'s Opp'n, Exh. 25 ¶ 7. Based on these observations, as well as "the usual customs and ordinary practice of the Phoster Pharmacy," Mindlin concludes that "the sole and exclusive brand of DES in the store was the Eli Lilly Brand, from the late 60s through the time [he] actually bought the store." *Id.* ¶ 8.

Eli Lilly argues that Mindlin's statements should be ignored because they do nothing more than confirm that Mindlin has no personal knowledge relevant to this case. Specifically, Eli Lilly notes that Mindlin does not state when in 1968 he began visiting Phoster Pharmacy, nor does he state the frequency of his visits. Def.'s Reply at 5. Without these details, Eli Lilly contends that Gassman "still has not established that Mindlin has any personal knowledge about the stocking and dispensing practices of Phoster's during the relevant time frame." *Id.* at 5-6.

While Eli Lilly's arguments may appeal to a jury, they are of no moment to this court for purposes of resolving the pending motion. The court is not only required to believe the competent evidence of Gassman, but must also grant all reasonable inferences in her favor. Accordingly, this court is satisfied that a jury question exists as to whether Gassman's injuries were caused by Eli Lilly's drugs. *Cf. McMahon v. Eli Lilly & Co.*, 774 F.2d 830, 832-34 (7th Cir. 1985) (affirming a directed verdict in favor of plaintiff when relevant pharmacy could not

remember particular brand, but “to the best of his knowledge,” the wholesaler thought that the store bought DES manufactured by Eli Lilly).

### III. CONCLUSION

For the aforementioned reasons, it is this 29th day of December, 2005, hereby

**ORDERED** that defendant’s motion for summary judgment [#11] is **DENIED**.

Henry H. Kennedy, Jr.  
United States District Judge

# **APPENDIX 19**

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

STEPHANIE CLAYTON,

Plaintiff,

v.

ELI LILLY AND COMPANY.

Defendant.

:  
:  
:  
:  
:  
:  
:  
:  
:  
:

Civil Action No.: 04-1363 (RMU)

Document No.: 12

ORDER

DENYING THE DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

For the reasons stated in the accompanying Memorandum Opinion, it is this 16th day of March, 2006.

ORDERED that the defendant's motion for summary judgment is DENIED.

SO ORDERED.

RICARDO M. URBINA

United States District Judge

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

STEPHANIE CLAYTON,	:		
	:		
Plaintiff.	:	Civil Action No.:	04-1363 (RMU)
	:		
v.	:	Document No.:	12
	:		
ELI LILLY AND COMPANY,	:		
	:		
Defendant.	:		

**MEMORANDUM OPINION**

**DENYING THE DEFENDANT'S MOTION FOR SUMMARY JUDGMENT**

**I. INTRODUCTION**

This matter comes before the court on the defendant's motion for summary judgment. The plaintiff brings this products liability and personal injury action alleging *in utero* exposure to a synthetic estrogen manufactured by the defendant. The defendant moves for summary judgment, arguing that the plaintiff cannot prove that she was exposed to its product. Because the plaintiff's evidence establishes a genuine issue of material fact as to whether the defendant caused her injuries, the court denies the defendant's motion for summary judgment.

**II. BACKGROUND**

**A. Factual Background**

The defendant, Eli Lilly and Company ("Eli Lilly") is engaged in the manufacturing, marketing, sale, promotion and distribution of pharmaceuticals throughout the United States. Compl. ¶ 2. The defendant formerly sold and distributed the drug diethylstilbestrol ("DES"), a drug used by millions of women to prevent miscarriage. DES was subsequently banned by the

FDA and recalled by manufacturers. Answer ¶ 2: Pl.'s. Opp'n to Def.'s Mot. for Summ. J. ("Pl.'s. Opp'n") at 1.

In 1964, the plaintiff's mother, Margaret White, was pregnant with the plaintiff in Birmingham, Alabama. Compl. ¶ 3, and took DES during her pregnancy. *Id.* Consequently, the plaintiff alleges she was exposed to DES *in utero*. *Id.* ¶ 4. The plaintiff claims that she has suffered injuries, including uterine and cervical malformations with resulting infertility, incurred medical expenses for care and treatment, and suffered physical and mental pain and suffering, and that her injuries were caused by her exposure to DES *in utero*. *Id.*

White filled her prescription for DES at the P&S Apothecary's Five Points West branch in Birmingham. Def.'s Mot. for Summ. J. ("Def.'s Mot.") at 12. Although White did not originally recall taking any medication during her pregnancy with the plaintiff, after reviewing materials provided by her daughter's attorneys, White recalled taking white, cross-scored DES tablets during her pregnancy. Pl.'s. Opp'n at 15; Def.'s Mot. at 11. The defendant manufactured white, cross-scored DES pills during the relevant time period in Birmingham. Pl.'s Opp'n at 15. Although nearly a hundred other companies also manufactured DES at that time, Def.'s Mot. at 5, the plaintiff contends that only the defendant manufactured a DES pill like the one the plaintiff's mother described. Pl.'s Opp'n at 15.

#### **B. Procedural Background**

On August 10, 2004, the plaintiff filed a complaint in the Superior Court of the District of Columbia. The defendant answered the complaint, but it also filed a notice to remove the case to this court pursuant on August 12, 2004. The case was subsequently removed to this court. On August 25, 2005, the defendant moved for summary judgment, arguing that the plaintiff cannot identify the defendant as the manufacturer of the synthetic estrogen that her mother took. Def.'s

Mot. at 1. The court now turns to the defendant's motion.

### III. ANALYSIS

#### A. Legal Standard for a Motion for Summary Judgment

Summary judgment is appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322, 91 L. Ed. 2d 265, 106 S. Ct. 2548 (1986); *Diamond v. Atwood*, 43 F.3d 1538, 1540 (D.C. Cir. 1995). To determine which facts are "material," a court must look to the substantive law on which each claim rests. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248, 91 L. Ed. 2d 202, 106 S. Ct. 2505 (1986). A "genuine issue" is one whose resolution could establish an element of a claim or defense and, therefore, affect the outcome of the action. *Celotex*, 477 U.S. at 322; *Anderson*, 477 U.S. at 248.

In ruling on a motion for summary judgment, the court must draw all justifiable inferences in the nonmoving party's favor and accept the nonmoving party's evidence as true. *Anderson*, 477 U.S. at 255. A nonmoving party, however, must establish more than "the mere existence of a scintilla of evidence" in support of its position. *Id.* at 252. To prevail on a motion for summary judgment, the moving party must show that the nonmoving party "failed to make a showing sufficient to establish the existence of an element essential to that party's case, and on which that party will bear the burden of proof at trial." *Celotex*, 477 U.S. at 322. By pointing to the absence of evidence proffered by the nonmoving party, a moving party may succeed on summary judgment. *Id.*

In addition, the nonmoving party may not rely solely on allegations or conclusory statements. *Greene v. Dalton*, 334 U.S. App. D.C. 92, 164 F.3d 671, 675 (D.C. Cir. 1999); *Harding v. Gray*, 9 F.3d 150, 154 (D.C. Cir. 1993). Rather, the nonmoving party must present specific facts that would enable a reasonable jury to find in its favor. *Greene*, 164 F.3d at 675. If the evidence "is merely colorable, or is not significantly probative, summary judgment may be granted." *Anderson*, 477 U.S. at 249-50 (internal citations omitted).

#### B. Alabama Law Applies to the Instant Action

As a preliminary matter, the defendant argues that the court should apply Alabama substantive law to this matter because the plaintiff was born in Alabama, was exposed *in utero* to DES in Alabama, and her mother allegedly filled her prescription in Alabama.<sup>1</sup> Def.'s Mot. at 7. Applying the District of Columbia's choice of law rules, the court determines that Alabama's substantive law applies to this action.

"In a diversity action, this Court sitting in the District of Columbia is obligated under *Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938), to apply the choice of law rules prevailing in this jurisdiction." *Dowd v. Calabrese*, 589 F. Supp. 1206, 1210 (D.D.C. 1984) (applying *Klaxon Co. v. Stentor Elec. Mfg. Co.*, 313 U.S. 487, 496 (1941)). For this analysis, the court looks to factors contained within the Restatement (Second) of Conflicts of Laws, including: "(a) the place where the injury occurred; (b) the place where the conduct causing the injury occurred; (c) the domicile, residence, nationality, place of incorporation and place of business of the parties; and (d) the place where the relationship is centered." *Jaffe v. Pallotta TeamWorks*, 374 F.3d 1223, 1227 (D.C. Cir. 2004) (citing RESTATEMENT (SECOND) OF CONFLICTS OF LAWS § 145). In

---

<sup>1</sup> The plaintiff does not oppose the defendant's argument.

making its choice of law, the court considers “which jurisdiction has the most significant relationship to the dispute.” *Id.*

Alabama has the most significant relationship to this case. Although the injury was diagnosed in Puerto Rico, the operative events giving rise to the injury, including the filling of the prescription, use of the drug and the plaintiff's *in utero* exposure to DES, occurred in Alabama. Because neither the domicile of the plaintiff nor the place of business or place of incorporation of the defendant is in the District of Columbia, the third factor does not weigh against applying Alabama law. Indeed, the only limited connection that this action has to the District of Columbia is that the defendant conducts some business in the District of Columbia. Given the substantial connection between this matter and Alabama and the lack of connection this matter has to the District of Columbia, Alabama substantive law applies to the plaintiff's claims. *Jaffe*, 374 F.3d at 1227; *see also Galvin v. Eli Lilly and Company*, Civil Action No. 03-1797, slip op. at 8 (D.D.C. June 10, 2005) (applying Kansas law in a DES case to determine whether plaintiff met her product identification burden because Kansas was the place of plaintiff's birth, the place of exposure, and the place where the DES prescription was filled).

### C. The Court Denies Defendant's Motion for Summary Judgment

The defendant moves for summary judgment, alleging that the plaintiff cannot establish that the DES her mother took was manufactured by the defendant. Def.'s Mot. at 1. Alabama products liability law requires the plaintiff to establish that the defendant's product caused her injuries. *Sheffield v. Owens-Corning Fiberglass Corp.*, 595 So. 2d 443, 450 (Ala. 1992) (stating that the “threshold requirement of any products liability action is identification of the injury-causing product and its manufacturer”) (citation omitted); *see also Turner v. Azalea Box Co.*, 508 So. 2d 253, 254 (Ala. 1987) (holding that a plaintiff in Alabama “must prove that the

defendant manufactured and/or sold the allegedly defective product"). Although the plaintiff must establish that the defendant's product caused her injuries by more than just speculation or conjecture, the plaintiff may use circumstantial evidence to prove the identity of the manufacturer. *Turner*, 508 So. 2d at 254; *see also Coca-Cola Bottling Co. v. Miller*, 249 So. 2d 630, 630 (Ala. Civ. App. 1971) (affirming the verdict for an individual who swallowed particles of glass contained in a soft drink bottle because the manufacturer did not offer any evidence to rebut the evidence showing it had manufactured, bottled, and distributed the soft drink at issue).

The defendant makes three main arguments to support its assertion that the plaintiff cannot prove that the defendant manufactured the drug to which she was exposed. First, the defendant argues that White's identification of the defendant as the manufacturer is not based on personal knowledge. Def.'s Mot. at 10. Second, the defendant contends that even if White did have personal knowledge, the plaintiff offers no proof that the defendant was the only manufacturer of white, cross-scored DES pills. *Id.* at 11. Finally, the defendant alleges that Lee Wade Sellers, a pharmacist at the P&S Apothecary's Five Points South branch and a witness for the plaintiff, has no personal knowledge of the stocking and dispensing practices at the P&S Apothecary Five Points West branch where White filled her prescription. *Id.* at 11-12. The defendant claims that these factors support summary judgment in its favor because the plaintiff cannot exclude the possibility she was exposed to another manufacturer's DES product. *Id.* at 6. The court addresses each of the defendant's argument in turn below.

#### **1. White's Personal Knowledge**

The defendant first argues that the plaintiff's mother, White, does not have the personal knowledge necessary to describe the tablet she took. Def.'s Mot. at 10. The defendant supports this claim with testimony from White's deposition, in which White stated that she had no

recollection of the pills she took until the plaintiff's attorneys sent her pictures of assorted DES pills. Def.'s Mot., Ex. 4 ("White Dep.") at 31:9-12. In ruling on a motion for summary judgment, the court does not weigh the evidence, but rather determines whether there is an issue for trial. *Anderson*, 477 U.S. at 249. White identified the pills she took as white and cross-scored after looking at photographs containing pictures of many types of DES pills. Pl.'s Opp'n, Ex. 10 ("Lewis Aff.") ¶ 4, 5. Although the defendant implies that White's identification is not reliable because it is based on the pictures her daughter's attorney gave her, Def.'s Mot. at 10, the reliability of White's memory goes to the weight of the evidence. "[M]emory gaps and doubts caused by the lapse of time go to the weight to be given the testimony," 27 FED. PRAC. & PROC. § 6023, and accordingly constitute a matter for the jury to decide. Accordingly, White's recollection, or lack thereof, is an issue for a jury to address.

## 2. White's Proof that Eli Lilly Manufactured the DES

The defendant also argues that even if White's description was based on personal knowledge, White's description alone is insufficient to exclude all other DES manufacturers. Def.'s Mot. at 11-12. While the defendant might be entitled to summary judgment if the plaintiff's only evidence consisted of White's description of the DES pill, *see Turner*, 508 So. 2d at 254, the plaintiff offers other evidence identifying the defendant as the manufacturer of the alleged drug. First, the plaintiff offers evidence suggesting the defendant was the exclusive manufacturer of the pill that White described – a small, round, white cross-scored 25mg DES tablet. *Id.* at 15. To support this claim, the plaintiff submits an affidavit stating that a review of nearly 300 DES photographs of 100 different brands of DES yielded no other DES pill with the same description as the defendant's pill. *Id.*: Pl.'s Opp'n, Ex. 17 ("Zhang Aff."). Although this evidence may not necessarily exclude every manufacturer's DES pill, this evidence is sufficient

to narrow the field of potential tortfeasors, which is all that is required under Alabama's product liability law. *Sheffield*, 595 So. 2d at 451 (stating that the plaintiff "must make it appear that it is more likely than not" that the defendant caused the plaintiff's injury) (quoting RESTATEMENT (SECOND) OF TORTS § 433B)

### 3. Sellers's Personal Knowledge

Last, the defendant argues that one of the plaintiff's witness, Sellers, does not have the personal knowledge necessary to describe the dispensing practices of the pharmacy where White filled her prescription. Def.'s Mot. at 10. Sellers worked at the P&S Apothecary Five Points South branch and was the pharmaceuticals buyer for all the P&S Apothecary stores. Pl.'s Opp'n, Ex. 12 ("Sellers Aff.") ¶¶ 2, 4. Sellers states that based on his observation, if a woman came into any P&S Apothecary store with a prescription for DES, the Eli Lilly brand would have been dispensed. Pl.'s Opp'n at 6-7; Pl.'s Opp'n, Ex. 14 ("Sellers Dep.") at 32:14-18. The defendant claims that Sellers's testimony should be disregarded because his testimony regarding the inventory supply of the Five Points West branch of P&S Apothecary, the store where White filled her prescription, is not based on personal knowledge. Def.'s Mot. at 11-12. To the contrary, however, Sellers has personal knowledge about orders placed in bulk quantity by the P&S Apothecary stores. Sellers Dep. at 9:17-22; Sellers Aff. ¶ 4. Furthermore, Sellers testified that P&S Apothecary only purchased from four local wholesalers, all of which sold the defendant's products. Sellers Aff. ¶ 7.

On a motion for summary judgment, the nonmoving party is entitled to every reasonable inference. *Anderson*, 477 U.S. at 255. Here, P&S Apothecary stores bought through the same four wholesalers. Sellers had knowledge of all orders placed in bulk quantity and Sellers only recalls seeing the defendant's brand of DES at his P&S Apothecary store. Sellers Aff. ¶¶ 6, 7.

Sellers, who acted as a buyer for all the P&S pharmacies, also states that any woman with a prescription for DES would have received the defendant's product. *Id.* ¶¶ 4, 6. For the purposes of this motion, the plaintiff is thus entitled to the reasonable inference that the stocking practices of the Five Points South branch corresponded to the stocking practices of the Five Points West branch.

In short, the evidence submitted by the plaintiff produces a genuine issue as to whether the plaintiff was exposed to the defendant's DES pill. FED. R. CIV. P. 56(c); *see also Celotex Corp.*, 477 U.S. at 322. Although the defendant argues that the plaintiff is required to exclude every DES manufacturer, Def.'s Reply at 5, the summary judgment standard does not require the nonmoving party "to discredit every conceivable alternative theory of causation." *Shields v. Eli Lilly and Co.*, 895 F.2d 1464, 1465 (D.C. Cir. 1990). The nonmoving party only need to produce evidence that would allow a reasonable juror "to find that the party proved the element at issue." *Id.* Here, the plaintiff has met her burden because she submits evidence suggesting that: (1) the defendant is the only company that manufactured a 25 mg, white, cross-scored DES pill during the relevant time period and (2) the pharmacy where her mother filled her prescription dispensed the defendant's DES pills. The defendant, moreover, fails to point to any other manufacturers of 25 mg white, cross-scored DES pills who sold their products in the Birmingham area.<sup>2</sup> Accordingly, the court denies the defendant's motion for summary judgment.

---

<sup>2</sup> The defendant cites to *Galvin v. Eli Lilly & Co.*, Civil Action No. 03-1797, slip op. (D.D.C. June 10, 2005) in support of its motion. Def.'s Reply at 3. In that case, however, the determinative factor for granting summary judgment was that the defendant offered into evidence a DES pill matching the same description as the pill identified by the plaintiff. *Id.* at 10. Here, the defendant has not offered such evidence. For this reason, the defendant's reliance on *Galvin* is misplaced.

#### IV. CONCLUSION

For the foregoing reasons, the court denies the defendant's motion for summary judgment. An order directing the parties consistent with this Memorandum Opinion is separately and contemporaneously issued this 16th day of March, 2006.

RICARDO M. URBINA  
United States District Judge

# **APPENDIX 20**

Virginia Camporesi

1

Volume: I

Pages: 1 to 76

Exhibits: None

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

-----  
KIMBERLY C. CUTONE and )  
ANTHONY CUTONE, ) CIVIL ACTION NO.:  
Plaintiffs, ) 04-CV-1365 (GK)  
vs. )  
ELI LILLY AND COMPANY, et al., )  
Defendants. )  
-----

DEPOSITION OF VIRGINIA CAMPORESI

Thursday, October 27, 2005

1:12 p.m.

Held at:

Foley Hoag, LLP

Seaport World Trade Center West

155 Seaport Boulevard, 13th Floor

Boston, MA 02210-2600

Reporter: Kathryn L. Santo

Virginia Camporesi

32

1 A. Cramping, light spotting. I went to the  
2 doctor's.

3 Q. When did that start during your  
4 pregnancy?

5 A. Near the beginning, within the first few  
6 months.

7 Q. What doctor did you go see?

8 A. Dr. McGovern, Sr.

9 Q. Did you have any bleeding, apart from the  
10 light spotting, in those first --

11 A. No.

12 Q. -- few months?

13 A. Just spotting and the cramps.

14 Q. When did the spotting begin?

15 A. Within the second month.

16 Q. How long did it last?

17 A. Well, when I went to the doctor's -- it  
18 was a few weeks before I went to the doctor's.

19 Q. Did the spotting continue throughout the  
20 pregnancy?

21 A. No.

22 Q. When did it stop?

23 A. After I started taking the medication,  
24 the diethylstilbestrol.

Virginia Camporesi

36

1 there? It's halfway down the page.

2 MR. LEVINE: I don't see where --

3 MS. DWYER: It's about halfway down under  
4 "Any medications or drugs taken during pregnancy."

5 A. I never took aspirin. I always took  
6 Tylenol.

7 Q. Do you recall taking capsules for blood?

8 A. No. I don't even know what that is.

9 Q. Of the medicines that you took while you  
10 were pregnant with Kimberly, did your doctor ever  
11 give you the medicines while you were in the  
12 office, give you the actual drug?

13 A. No.

14 Q. Did you ever have any problems with these  
15 medicines while you were pregnant with Kimberly?

16 A. Problems? No.

17 Q. What were you prescribed, if anything, to  
18 help maintain your pregnancy with Kimberly?

19 A. Diethylstilbestrol.

20 Q. Who prescribed that to you?

21 A. Dr. Philip McGovern, Sr.

22 Q. How do you know he prescribed you  
23 diethylstilbestrol?

24 A. Because he said the word, and it was

Virginia Camporesi

37

1 written on the prescription.

2 Q. What did Dr. McGovern say to you --

3 A. He told --

4 Q. -- when he gave you the  
5 diethylstilbestrol?

6 A. He told me he was going to give me  
7 diethylstilbestrol to help stop my miscarriage.

8 Q. Had you ever had a miscarriage before?

9 A. No.

10 Q. When in your pregnancy with Kimberly did  
11 you begin taking stilbestrol?

12 A. It was a couple of months along.

13 Q. You started to tell me about what  
14 Dr. McGovern said when he first prescribed the  
15 diethylstilbestrol. Can you remember other -- what  
16 else was said during that conversation?

17 A. Well, I was going to have a miscarriage  
18 if I didn't take some -- you know, that medicine.

19 Q. Did you know what diethylstilbestrol was  
20 at the time?

21 A. No.

22 Q. What form did you take diethylstilbestrol  
23 in?

24 A. What do you mean?

Virginia Camporesi

45

1 you ever consulted with your daughter's attorney  
2 about what the pill looked like?

3 A. "Consulted"?

4 Q. Have you ever talked to your daughter's  
5 attorney about what the pill looked like?

6 A. When they asked me.

7 Q. When did they ask you?

8 A. When they contacted me -- when was it --  
9 about two years ago.

10 Q. Who contacted you?

11 A. The law office, Levine.

12 Q. Do you remember who you spoke with?

13 A. Aaron Levine.

14 Q. What did you tell Mr. Levine when you  
15 first spoke to him about the pill?

16 A. I described it.

17 Q. How did you describe it when you first  
18 spoke to Mr. Levine about the pill?

19 A. It's a small, round, white pill with the  
20 cross on it.

21 Q. And that conversation occurred two years  
22 ago?

23 A. Yes, approximately.

24 Q. Has anyone ever showed you pictures of

Virginia Camporesi

47

1 A. Marcella.

2 Q. What was said during that conversation?

3 A. We discussed the medication that I took.  
4 I described the pill again.

5 Q. What was said about the photographs  
6 during that conversation?

7 A. The photographs? She asked if I  
8 recognized anything in the photographs. And I saw  
9 it right away, the diethylstilbestrol.

10 Q. What did that look like in the  
11 photograph?

12 A. Like the pill I took.

13 Q. What did the photograph itself look like?

14 A. The photograph itself? It was a round,  
15 white pill with a crossbar on it.

16 Q. Were there any other pills in the  
17 picture?

18 A. In that picture, it was just that. There  
19 were other pictures.

20 Q. How many pictures did you see?

21 A. Oh, many. About, maybe, six pages of  
22 pictures.

23 Q. Was there one picture on each page, or  
24 did the pages have multiple pictures?

Virginia Camporesi

48

1 A. Some had multiples.

2 Q. Okay. Let's go through what these  
3 pictures looked like then. You said there's about  
4 six pages. So to the extent you remember, let's  
5 just start with the first page of pictures. What  
6 was on that page?

7 A. Many different kinds of pills.

8 Q. What was on the second page of pictures?

9 A. Same thing. Many different kinds.

10 Q. What was on the third page of pictures?

11 A. It was a picture of the -- it had pennies  
12 and a pencil, and it had the white pill with the  
13 crossbar on it. It had a couple of them.

14 Q. It had a couple of pills or a couple --

15 A. Yes.

16 Q. -- of other objects?

17 A. There were pennies, a pencil, and a bunch  
18 of the pills.

19 Q. What did those pills look like?

20 A. The round, white pill with the crossbar.

21 MR. LEVINE: Are you saying "bar"?

22 THE WITNESS: Crossbar, whatever.

23 MR. LEVINE: Bar?

24 THE WITNESS: Yes.

Virginia Camporesi

55

1 how you describe texture.

2 Q. Was the pill hard or soft?

3 A. Hard.

4 Q. Was it coated like an M&M or not coated?

5 A. No. No coating.

6 Q. Were there any markings on the pill or  
7 imprints?

8 A. No.

9 MR. LEVINE: Other than what you've  
10 previously described.

11 THE WITNESS: Right.

12 A. The cross.

13 Q. What did the bottle containing the  
14 diethylstilbestrol look like?

15 A. Just a brown bottle, brown prescription  
16 bottle.

17 Q. It was a brown prescription bottle from  
18 the pharmacy? Their bottle?

19 A. Yes.

20 Q. What did the label on the pharmacy bottle  
21 say?

22 A. It said the name of the medication,  
23 diethylstilbestrol. It had my name on it. I'm not  
24 sure of the -- the strength of the pill.

# **APPENDIX 21**

**1969•PDR**

**Published by MEDICAL ECONOMICS, INC.**

**TWENTY-THIRD EDITION**

**PHYSICIANS'  
DESK REFERENCE**

**to  
PHARMACEUTICAL SPECIALTIES  
and BIOLOGICALS**

***For the Physician's Desk***

**1  
9  
6  
9  
  
P  
D  
R**

**Fungus Antigens**

MMP Mold Allergens (Hollister-Stier)

**Glucosuria Test**

Tes-Tape (Lilly)

**Histoplasmin**

Histoplasmin (Parke, Davis)

Histoplasmin, Tine Test (Lederle)

**Hypopituitarism**

Metopirone (Ciba)

**Kidney Function**

Phenolsulfonphthalein Injection (Hynson, Westcott &amp; Dunning)

**Liver Function**

Bromsulphalein (Hynson, Westcott &amp; Dunning)

Cardio-Green (Hynson, Westcott &amp; Dunning)

Synkayvite Preparations (Roche)

**Myasthenia Gravis**

Mestinon Syrup (Roche)

Mestinon Tablets (Roche)

Mestinon Timespan (Roche)

Prostigmin Methylsulfate Injectable (Roche)

Tensilon (Roche)

**Pregnancy Test**

Deluteval 2X (Squibb)

Gestest Tablets (Squibb)

Pro-Duosterone (Roussel)

Prostigmin Methylsulfate Injectable (Roche)

Provera (Upjohn)

**Premature Rupture of Fetal Membranes**

Vernitest (Fuller)

**Progesterone Production**

Delalutin (Squibb)

Deluteval 2X (Squibb)

Vernitest (Fuller)

**Schick Test**

Diphtheria Toxin for Schick Test (Wyeth)

Schick Test (Wyeth)

**Stool Specimens**

Fleet Enema (Fleet)

Phospho-Soda (Fleet)

**Sugar Test, Urine**

Tes-Tape (Lilly)

**Thyroid Function**

Thyropar (Armour)

Triosorb-131 (Abbott)

**Thyrotropic Hormone**

Thyropar (Armour)

**Tuberculosis**

Sterneedle (Panray)

Tuberculin, Mono-Vacc Test (Lincoln)

Tuberculin, Purified Protein Derivative (Parke, Davis)

Tuberculin, Tine Test (Rosenthal) (Lederle)

**Unsaturated Iron-Binding Capacity**

Irosorb-59 (Abbott)

**Vaginitis**

Nickerson's Medium (Ortho)

Vaginoptic (Schmid)

**Diastase**

Arco-Lase (Arco)

**Diazepam**

Valium M 75 (Winthrop)

Hypaque-M 90 (Winthrop)

**Dibucaine**

Valium Injectable (Roche)

Valium Tablets (Roche)

**Dibucaine Hydrochloride**

Nupercainal (Ciba)

Nupercaine Heavy Solution (Ciba)

Nupercaine hydrochloride (Ciba)

Nupercaine hydrochloride 1:1500 (Ciba)

Nuporals (Ciba)

**Dichloralphenazone**

Midrin (Carnrick)

**Dicyclomine Hydrochloride**

Bendectin (Merrell)

Bentyl Hydrochloride-Capsules, Tablets &amp; Syrup (Merrell)

Bentyl Hydrochloride w/Phenobarbital Capsules, Tablets &amp; Syrup (Merrell)

Kolantyl (Merrell)

**Dienestrol**

AVC Cream w/Dienestrol (National Drug)

AVC Suppositories w/Dienestrol (National Drug)

Dienestrol Cream (Ortho)

Estan (White)

Synestrol Tablets (White)

**Dietary Supplements***see under Amino Acid Preps., Calcium & Calcium-Phosphorus Preps., Fat Emulsions, Foods (Dietetic), Hematinics, Vegetable Oil (Preps.) & Vitamin Preps.***Diethylpropion**

Tenuate (Merrell)

Tenuate Dospan (Merrell)

Tepanil (National Drug)

Tepanil Ten-Tab (National Drug)

**Diethylstilbestrol**

Acnestrol Lotion (Dermik)

Dicorvin Tablets (Amfre-Grant)

Diethylstilbestrol (Lilly)

Furacin-E Urethral Inserts (Eaton)

Gynben Vaginal Inserts &amp; Cream (Bentex)

Quinette (Arnar-Stone)

Sulphostrol (Dome)

**Diets (Liquid)**

LO/SO Liquid (Dairy House)

Sustagen (Mead Johnson)

**Digallolyl Trioleate**

SunStick Lip Protectant (Texas Pharmacal)

SunSwept Cream (Texas Pharmacal)

**Digestants**

Arco-Lase (Arco)

Arco-Lase Plus (Arco)

Butibel-Zyme (McNeil)

Carica-Bile Tablets (Rexall)

Combichole (Trout)

Convertin Tablets (Ascher)

Convertin-H Tablets (Ascher)

Converzyme (Ascher)

Cotazym (Organon)

Dactilase (Lakeside)

Digestant (Canright)

Digolase (Boyle)

Donnazyme (Robins)

Entozyme (Robins)

Enzypan (Norgine)

Festal (Hoechst)

Festalan (Hoechst)

Gastroenterase (Wampole)

**Kanulase (Dorsey)**

Kanumodic (Dorsey)

Karyzyme (Kremers-Urban)

Karyzyme (Kremers-Urban)

Lipan (Spirit)

Mallenzyme (Mallard)

Pentazyme (Ulmer)

Phazyme (Reed &amp; Carnrick)

Phazyme w/Phenobarbital (Reed &amp; Carnrick)

Pro-Gestive (Nutrition Control)

**Digitalis Glycoside Preparations**

Acyland (Sandoz)

Cediland (Sandoz)

Crystodigin (Lilly)

Davoxin (Davies Rose Hoyt)

Digitaline Native (Fougera)

Digoxin Tablets (Rexall)

Gitaligin Tablets (Schering)

Lanoxin (B.W. &amp; Co.)

Myodigin (Davies Rose Hoyt)

Purodigin (Wyeth)

**Digitalis Preparations**

Crystodigin (Lilly)

Davoxin (Davies Rose Hoyt)

Digitara (Upjohn)

Digoxin Tablets (Rexall)

Myodigin (Davies Rose Hoyt)

Pil-Digis (Davies Rose Hoyt)

**Digitoxin**

Crystodigin (Lilly)

Digitaline Native (Fougera)

Myodigin (Davies Rose Hoyt)

Purodigin (Wyeth)

**Digoxin**

Davoxin (Davies Rose Hoyt)

Digoxin Tablets (Rexall)

Lanoxin (B.W. &amp; Co.)

Ultra-ject Disposable Syringe (Century)

**Dihydrocodeine Bitartrate**

Drocogetic No. 3 (Century)

Synalgos Preparations (Ives)

**Dihydrocodeinone Bitartrate**  
*(see under Hydrocodone Bitartrate)***Dihydroergotamine**

D.H.E. 45 (Sandoz)

**Dihydromorphinone Hydrochloride**  
*(see also under Hydromorphone Hydrochloride)*

Dilaudid Cough Syrup (Knoll)

Dilocol (Table Rock)

Ultra-ject Disposable Syringe (Century)

**Dihydrostreptomycin Sulfate**

Kectil Suspension (Bristol)

Polymagma Suspension (Wyeth)

Polymagma Tablets (Wyeth)

**Dihydrotrachysterol**

Hytakerol (Winthrop)

**Dihydroxy Aluminum Aminoacetate**

Aluscop (Westerfield)

Alzinox (Smith, Miller &amp; Patch)

Alzinox Compound (Smith, Miller &amp; Patch)

Donnalate (Robins)

Robalate (Robins)

**Dihydroxyanthraquinone**

Doxan (Hoechst)

Doxidan (Hoechst)

Doxinate w/Danthron (Hoechst)

**Dihydroxyanthraquinone (1,8)**  
*(See under Danthron)***Dihydroxypropylthiophylline**

Emfascem Improved (Saron)

(phenaglycodol, Lilly) with the established analgesic advantages of Darvon and A.S.A. Clinical and pharmacologic studies show that Ultrán enhances and prolongs the analgesic activity of Darvon when pain is accompanied by anxiety.

Each Pulvule contains—  
 Darvon® 32 mg.  
 (propoxyphene hydrochloride, Lilly)  
 A.S.A.® 325 mg.  
 (aspirin, Lilly)  
 Ultrán® 150 mg.  
 (phenaglycodol, Lilly)

Side-effects seen following administration of Darvon in adequate dosage to a large series of patients are qualitatively similar to those produced by the same or similar doses of codeine; however, from a quantitative viewpoint, the side-effects associated with Darvon are less than those of codeine.

Indications: Darvon is indicated for the reduction or amelioration of pain. It is of particular value for pain associated with recurrent or chronic disease. This is true even in such conditions as migraine, in which specific therapy sometimes fails to produce immediate or complete relief. Continued use has revealed no evidence of functional or pathological changes. Darvon does not reduce fever or diminish inflammatory reactions.

Darvon Compound and Darvon Compound-65 provide the total analgesic effects of Darvon and A.S.A. Compound plus the anti-inflammatory and antipyretic activity of salicylates. This combination may be especially valuable in the symptomatic relief of such conditions as headache, dysmenorrhea, or various inflammatory states, e.g., arthritis and fibrositis.

Darvon with A.S.A. is made available for use by physicians who prefer an analgesic without phenacetin and caffeine.

Clinical studies indicate that the analgesic effects of Darvon are enhanced when it is given concurrently with Ultrán. These studies also suggest that Darvo-Tran may provide skeletal-muscle relaxation. This presumptive evidence is based upon the fact that Darvo-Tran has been found to be more effective than Darvon per se or Darvon Compound in such diagnostic categories as arthritic conditions, tension headache, low-back syndromes, whiplash injuries, dentistry and oral surgery procedures, postpartum discomfort, and postoperative pain.

Contraindications: Although no definite contraindications to the use of Darvon have been reported, any known hypersensitivity to any of the ingredients in Darvon preparations is a contraindication. Therapeutic doses have produced no demonstrable effects on respiration, blood pressure, or reflex activity.

The presence of acute or chronic disease has not produced unusual responses during therapy with Darvon.

The concomitant administration of Darvon and orphenadrine-containing compounds is not recommended.

Caution should be exercised in the administration of Ultrán to patients who are depressed.

Warnings: Salicylates should be used with caution in the presence of gastric ulcer. The prolonged and excessive use of phenacetin-containing products may aggravate or produce renal disease.

Use in Pregnancy—The safety of the use of Darvon during pregnancy has not been established. The potential hazards of the drug must be weighed against the possible benefits.

Use in Children—Darvon should not be used in children since adequate data to establish safe conditions of use are lacking.

Precautions: Patients who have received other analgesic drugs for long periods of time may have developed physical dependence on those medications. The sudden substitution of Darvon for analgesics to which patients are addicted will allow

withdrawal symptoms to develop. These symptoms are not produced by Darvon and may be avoided by gradually reducing the dose of the old medication as Darvon is substituted.

Although accumulated evidence suggests that Ultrán is not habit-forming or addictive, it is recommended that patients on tranquilization therapy, particularly over prolonged periods, be under periodic medical supervision. Certain patients may place inordinate dependence on any medication which alleviates discomfort, and these individuals may transgress the bounds of prescribed dosage.

Patients driving an automobile or operating hazardous machinery should be advised that mental alertness or physical coordination may be decreased in some persons. The administration of Ultrán with other C.N.S. depressants and/or alcohol may result in additive effects.

Adverse Reactions: Such side-effects as dizziness, headache, sedation, somnolence, paradoxical excitement and insomnia, skin rash, and gastro-intestinal disturbances (including nausea, vomiting, abdominal pain, and constipation) occur with the recommended doses of Darvon.

When recommended doses are given, euphoria and tolerance have been reported rarely. Dependence (addiction) has not been reported with therapeutic dosages.

In some instances, gastric irritation accompanying the use of Darvon Compound, Darvon with A.S.A., or Darvo-Tran may be directly attributable to the salicylate in the preparation. In such cases, it is suggested that the medication be taken with food or a small amount of milk or discontinued.

Other side-effects which have been reported with Darvo-Tran include vertigo, drowsiness, gynecomastia, headache, sedation, somnolence, insomnia, and/or excitation.

Administration and Dosage: Darvon is given orally. The usual adult dosage is 65 mg. three or four times daily; however, some physicians prefer the 32-mg. dose for certain patients. The usual dose may be given alone or with other medication, as required for the relief of pain.

The usual dosage of Darvon Compound is 1 or 2 Pulvules three or four times daily.

The usual dosage of Darvon Compound-65 or of Darvon with A.S.A. is 1 Pulvule three or four times daily.

The suggested adult dosage of Darvo-Tran is 1 Pulvule three or four times daily. When pain, with or without anxiety, is severe, 2 Pulvules three or four times daily may be indicated. It should be remembered that two Pulvules Darvo-Tran will provide a 300-mg. dose of Ultrán, which may predispose to mild drowsiness in certain hypersensitive individuals. Two Pulvules also provide 64 mg. of Darvon, the amount currently recommended when moderate to severe pain exists.

Overdosage: If an overdose of Darvon is accidentally or intentionally ingested, analeptic drugs (e.g., amphetamine or caffeine with sodium benzoate) should not be used, because fatal convulsions may be produced. Animal studies and clinical experiences have demonstrated that the signs and symptoms of acute intoxication with Darvon, including muscle fasciculations, convulsions, and respiratory depression, are antagonized by nalorphine hydrochloride and levallorphan tartrate. The dosages recommended in the package literature of these antagonists should be followed and repeated as often and as long as is necessary to counteract the reappearing symptoms of overdosage.

Gastric lavage to remove unabsorbed medication is indicated. Symptomatic supportive treatment should also be given as required.

How Supplied: (R) Pulvules Darvon® (Propoxyphene Hydrochloride Capsules, U.S.P.): No. 364, H02,\* 32 mg. (No. 4,

Light-Pink Opaque), in bottles of 100 and 500, in 10 strips of 10 individually labeled blisters each containing 1 Pulvule (ID100), and in strip packages of individually sealed Pulvules (DS1000); No. 365, H03,\* 65 mg. (No. 3, Light-Pink Opaque), in bottles of 100 and 500, in 10 strips of 10 individually labeled blisters each containing 1 Pulvule (ID100), and in strip packages of individually sealed Pulvules (DS1000). Dated items.

(R) Pulvules No. 368, Darvon® Compound (propoxyphene hydrochloride, aspirin, phenacetin, and caffeine, Lilly), H05\* (No. 0, Light-Pink Opaque Body, Light-Gray Opaque Cap), in bottles of 100 and 500, in 10 strips of 10 individually labeled blisters each containing 1 Pulvule (ID100), and in strip packages of individually sealed Pulvules (DS1000). Dated item.

(R) Pulvules No. 369, Darvon® Compound-65 (propoxyphene hydrochloride, aspirin, phenacetin, and caffeine, Lilly), H06\* (No. 0, Red Opaque Body, Light-Gray Opaque Cap), in bottles of 100 and 500, in 10 strips of 10 individually labeled blisters each containing 1 Pulvule (ID100), and in strip packages of individually sealed Pulvules (DS1000). Dated item.

(R) Pulvules No. 366, Darvon® with A.S.A.® (propoxyphene hydrochloride with aspirin, Lilly), H04\* (No. 0, Red Opaque Body, Light-Pink Opaque Cap), in bottles of 100 and 500, in 10 strips of 10 individually labeled blisters each containing 1 Pulvule (ID100), and in strip packages of individually sealed Pulvules (DS1000). Dated item.

(R) Pulvules No. 377, Darvo-Tran® (propoxyphene hydrochloride and aspirin with phenaglycodol, Lilly), H11\* (No. 0, Light-Pink Opaque Body, Maroon Opaque Cap), in bottles of 100 and 500. [030568]

#### DIETHYLSTILBESTROL ENSEALS®, SUPPOSITORIES, AND TABLETS

Description: Diethylstilbestrol is a crystalline synthetic estrogenic substance capable of producing all the pharmacologic and therapeutic responses attributed to natural estrogens.

Indications: Tablets and Enseals Diethylstilbestrol are indicated for the relief of symptoms of the menopause; in senile vaginitis; for the relief or prevention of painful engorgement of the breasts postpartum; for control of functional uterine bleeding; in carcinoma of the prostate; and in mammary carcinoma of postmenopausal women.

Suppositories Diethylstilbestrol are indicated in postmenopausal and senile vaginitis, especially when menopausal symptoms are not present.

Contraindications: The contraindications to diethylstilbestrol administration are the same as to estrogen therapy in general. Estrogens should not be administered in the absence of a positive indication, and they should be avoided in premenopausal women with carcinoma of the breast and in all women with genital malignancy. A family history of a high incidence of breast or genital malignancy may be a contraindication.

In young patients in whom bone growth is not complete, estrogen therapy is contraindicated because of its effect on epiphyseal closure.

Suspected or known hepatic disease should be regarded as a contraindication to prolonged estrogen therapy.

Warning: Because of possible adverse reaction on the fetus, the risk of estrogen therapy should be weighed against the

Continued on next page

\*Identifi-Code® symbol—Newly manufactured capsules and tablets and the labels of powders for oral suspension and suppositories will bear Identifi-Code symbols. However, a period of time will elapse before existing stocks of noncoded products are exhausted.

Lilly—Cont.

possible benefits when diethylstilbestrol is considered for use in a known pregnancy. **Precautions:** Diethylstilbestrol is a potent drug, and caution must be employed in its use. Indiscriminate or injudicious administration may be dangerous. Patients receiving the drug should be under continuous medical supervision. In women, the breasts and pelvic organs should be examined before treatment is begun and at intervals during therapy.

Diethylstilbestrol should be administered with caution to a patient with bone, renal, or other disease involving calcium or phosphorus metabolism, since estrogens are known to affect metabolism of these substances. Conditions such as epilepsy, migraine, asthma, and cardiac or renal dysfunction require careful observation because the drug may produce some degree of fluid retention. Liver, thyroid, or adrenal function tests should not be performed until estrogen therapy has been discontinued for two months.

**Adverse Reactions:** As with natural estrogens, unpleasant side-effects have been noted following diethylstilbestrol therapy. Most common is the occurrence of nausea, which may be severe enough to lead to vomiting. The incidence of nausea appears to differ significantly among various types of patients. Pregnant and postpartum women seem the least susceptible.

Nausea and vomiting are most easily produced in the group of menopausal women. When dosage is minimal, nausea is infrequent and transient. When larger doses are given (1 mg. or more daily), and particularly when they are administered initially, nausea and vomiting are common in the menopausal group. Men and nonpregnant women form an intermediate group, nausea in them being relatively uncommon from doses of 3 to 5 mg. daily.

Continuous therapy over long periods of time, even in low dosage, may produce endometrial hypertrophy and uterine bleeding. This can be prevented in most instances by minimal dosage and by cyclic interruption of therapy when treatment must be prolonged. Porphyria cutanea tarda is also possible with prolonged use of the drug.

Other side-effects occasionally noted include abdominal distress or pain, breast tenderness and engorgement, anorexia, diarrhea, lassitude, paresthesia, vertigo, headache, anxiety, insomnia, thirst, scotomata, cutaneous rashes, purpura, and allergic reactions of various types. Side-effects may be expected to disappear on reduction of dosage or withdrawal of medication.

**Administration and Dosage:** *Oral*—In menopausal symptoms, 0.2 to 0.5 mg. daily, increased as needed. In senile vaginitis, 0.5 mg. daily. In painful engorgement of the breasts postpartum, 5 mg. one to three times daily for a total of 30 mg. In functional uterine bleeding, usually 5 mg. three to five times daily until bleeding ceases. In carcinoma of the prostate, 1 to 3 mg. daily, increased in advanced cases; later, the dose may be reduced to an average of 1 mg. daily. In cancer of the breast, 15 mg. daily. *Vaginal*—One 0.5-mg. suppository inserted at bedtime each night, or less frequently as needed. For maintenance, a 0.1-mg. suppository periodically may be adequate.

**How Supplied:** (R) *Enseals*—Diethylstilbestrol Tablets, U.S.P. (Enteric): No. 46, A19,\* 0.1 mg., No. 47, A20,\* 0.25 mg., No. 48, A21,\* 0.5 mg., and No. 49, A22,\* 1 mg., in bottles of 100 and 1,000; No. 85, A33,\* 5 mg., in bottles of 100, 500, and 1,000; No. 90, A34,\* 25 mg., in bottles of 100 and 500. Dated items.

(R) *Suppositories*—Diethylstilbestrol Suppositories, U.S.P. (Vaginal): No. 14, S07,\* 0.1 mg., and No. 15, S09,\* 0.5 mg., in packages of 6 and 50. In addition to the diethyl-

stilbestrol, these suppositories contain glycerin, gelatin, polysorbate 20, and propylene glycol.

(R) *Tablets*—Diethylstilbestrol Tablets, U.S.P.: No. 1646, J49,\* 0.1 mg., in bottles of 100 and 1,000; No. 1647, J50,\* 0.25 mg., in bottles of 100; No. 1648, J51,\* 0.5 mg., and No. 1649, J52,\* 1 mg., in bottles of 100 and 1,000; No. 1685, J54,\* 5 mg., in bottles of 100 and 1,000 and in 10 strips of 10 individually labeled blisters each containing 1 tablet; No. 1724, T70,\* 25 mg. (cross-scored), in bottles of 100. Dated items.

[120467]

**DIGITOXIN**, see Crystodigin® (digitoxin, Lilly).

**DIPHTHERIA AND TETANUS TOXOIDS AND PERTUSSIS VACCINE COMBINED**, see Tri-Solugen® (diphtheria and tetanus toxoids and pertussis vaccine combined, alum precipitated, Lilly).

• **DOLOPHINE® HYDROCHLORIDE** B (methadone hydrochloride) Injection, U.S.P.

**AMPOULES**

**Description:** Dolophine Hydrochloride is 4,4 - diphenyl - 6 - dimethylamino - heptanone-3 hydrochloride. It is a white, crystalline material and is water soluble. It is similar to morphine in effect, but it has a more prolonged duration of action as a result, at least partially, of greater lipid solubility.

**Indications:** Dolophine Hydrochloride is indicated when an analgesic effect is required, especially in the relief of postsurgical pain and pain associated with renal colic, metastatic lesions of malignant tumors, fractures, etc. When chronic administration of potent analgesics is necessary, Dolophine Hydrochloride is preferable to morphine since it induces less physical dependence. It is not recommended for the control of mild pain in place of less potent analgesic drugs, such as the salicylates or even codeine.

**Contraindications and Precautions:** Although Dolophine Hydrochloride has been used successfully in obstetric patients, it should be given with caution in the intrapartum period. Sedatives or other drugs which may depress fetal respiration should not be administered if delivery is anticipated before most of the drug will be eliminated from the fetal circulation. The risk is increased if the infant is premature or if general anesthesia is used for delivery.

After prolonged administration resulting in the development of considerable tolerance, withdrawal of Dolophine Hydrochloride is followed by a mild but definite abstinence syndrome.

**Warning:** Dolophine Hydrochloride has addictive characteristics, and a narcotic prescription is required.

**Adverse Reactions:** The most common side-effects produced by Dolophine Hydrochloride are nausea and vomiting. Other less bothersome symptoms include dizziness, dryness of mouth, and miosis. Nausea and vomiting have appeared most often with large doses and are of the type characteristically observed following administration of morphine.

The cumulative effect of Dolophine Hydrochloride seems evident. Although the first doses may be well tolerated, nausea may appear after several have been given. It is recommended that the drug be administered only when needed for control of pain. Side-effects also seem to be more prominent in ambulatory patients and in those who are not suffering acute pain. In such individuals, the lower doses are advisable.

**Administration and Dosage:** Contents of Ampoules Dolophine Hydrochloride may be administered subcutaneously or intramuscularly.

Parenteral doses of Dolophine Hydrochloride range from 2.5 to 10 mg., according to the severity of pain, and should be re-

peated only when pain returns. Excessive frequency of administration and size of dose should be avoided.

**Overdosage:** The primary symptom of overdosage is respiratory depression. Other symptoms are drowsiness, sweating, mental depression, delirium, hallucinations, circulatory collapse, and coma. Nalorphine hydrochloride (Nalline® HCl) provides specific therapy for overdosage. It should be repeated when necessary to counteract respiratory depression. General management should consist in symptomatic and supportive therapy, which may include administration of oxygen and intravenous fluids and maintenance of body temperature.

**How Supplied:** • (R) *Ampoules Dolophine® Hydrochloride (Methadone Hydrochloride Injection, U.S.P.):* No. 456, 10 mg., 1 cc., in packages of 12 and 100. Each cc. contains methadone hydrochloride, 10 mg., and sodium chloride, 0.9 percent. Sodium hydroxide and/or hydrochloric acid may have been added during manufacture to adjust the pH. No. 435, 10 mg. per cc., 20 cc., rubber-stoppered, in single ampoules (10 per carton) and in packages of 25. Each cc. contains methadone hydrochloride, 10 mg., and sodium chloride, 0.9 percent, with chlorobutanol (chloroform derivative), 0.5 percent, as a preservative. Sodium hydroxide and/or hydrochloric acid may have been added during manufacture to adjust the pH. Dated items.

• Narcotic order required. [021668]

• **DOLOPHINE® HYDROCHLORIDE** B (methadone hydrochloride) SYRUP AND TABLETS

**Description:** Dolophine Hydrochloride (4,4 - diphenyl - 6 - dimethylamino - heptanone-3 hydrochloride) is an effective, stable antitussive and analgesic, 10 mg. of which are comparable in analgesic potency to morphine sulfate, 15 mg. (¼ grain).

**Indications:** As an antitussive, it is of benefit in the control of cough associated with the common cold, whooping cough, or chronic tuberculosis.

As an analgesic, Dolophine Hydrochloride is especially useful in relieving postsurgical pain and pain associated with renal colic, metastatic lesions of malignant tumors, fractures, etc.

**Contraindications and Precautions:** Although Dolophine Hydrochloride has been used successfully in obstetric patients, it should be given with caution in the intrapartum period. Sedatives or other drugs which may depress fetal respiration should not be administered if delivery is anticipated before most of the drug will be eliminated from the fetal circulation. The risk is increased if the infant is premature or if general anesthesia is used for delivery. After prolonged administration resulting in the development of considerable tolerance, withdrawal of Dolophine Hydrochloride is followed by a mild but definite abstinence syndrome.

**Warning:** Dolophine Hydrochloride has addictive characteristics, and a narcotic prescription is required.

**Adverse Reactions:** Nausea and vomiting, dizziness, dryness of mouth, and miosis may occur. Nausea and vomiting appear most often with large doses and seem to be present when the medication is given more frequently than is required to control pain (this is suggestive of cumulation). It is suggested that the drug be administered only when needed for control of pain. Side-effects seem to be more prominent in ambulatory patients and in those who are not suffering acute pain. In such individuals, the lower doses are recommended.

**Administration and Dosage:** Antitussive—Adults, ½ to 1 teaspoonful of the syrup every four to six hours (do not overdose). Children, three to twelve years, ¼ to ½ teaspoonful every four to six hours (do not overdose).

**Analgesic**—Adults, moderate pain, 2.5 mg.

# **APPENDIX 22**

Boston University

Center for Educational Development in Health  
53 Bay State Road  
Boston, Massachusetts 02215  
617/353-4528  
Fax: 617/353-7417  
E-mail: [asegall@bu.edu](mailto:asegall@bu.edu)  
[hvanders@bu.edu](mailto:hvanders@bu.edu)



April 13, 2004

To whom it may concern

I agree to analyze, aggregate and summarize data from the pharmacist's survey regarding dispensing of Diethylstilbestrol (DES) in the 1960's. Three hundred surveys are being sent out to Massachusetts' pharmacists who practiced in the 1960s. Remedy Pharmacy When surveys are returned, Management Services, Inc will send the completed surveys to me for analysis.

I will summarize each respondent's survey as follows:

- Name and address of pharmacist
- Pharmacy school attended
- When licensed to practice pharmacy in Massachusetts
- Name of pharmacy where respondent practiced
- Location of pharmacy (city or town)
- Brand or brands of Diethylstilbestrol (DES) ordinarily or customarily dispensed in the 5mg or 25mg size (pregnancy sizes)

For this service I will charge \$800/day for four or five 5 days or \$4,000:maximum. I will write a report on the findings and sign my name to the report.

A handwritten signature in cursive script, reading "Hannelore Vanderschmidt".

Hannelore Vanderschmidt, PhD  
Co-Director

Boston University

Center for Educational Development in Health  
53 Bay State Road  
Boston, Massachusetts 02215  
617/353-4528  
Fax: 617/353-7417  
E-mail: [asegall@bu.edu](mailto:asegall@bu.edu)  
[hvanders@bu.edu](mailto:hvanders@bu.edu)



August 26, 2004

Mr. Harold Sparr, R.Ph., D.Ph., M.S.,

P.O. Box 66

Otis, Massachusetts 01253

Dear Harold:

You have asked that I enter and analyze the responses to a questionnaire survey seeking to determine scientifically the market share in Massachusetts of the prescription drug Diethylstilbestrol (DES 5 & 25<sub>mg</sub>), in the state in the 1960's. This assignment was further detailed in a letter from Aaron M. Levine to you dated May 5, 2004 (see Attachment 4). As a practicing pharmacist of forty-five years and the former president of the Massachusetts Board of Registration in Pharmacy you have advised me that in the fifteen years between 1955 and 1970 the market for this drug remained relatively stable, although the popularity of the drug slowly decreased.

Because we are attempting to determine market shares forty years later, when so many of the pharmacists who were practicing then may have moved, retired or died, a target population of those pharmacists who were practicing in the period 1963 to 1967 was determined to be the most reasonable population that would be both available and knowledgeable at the same time typical and timely as to this query.

I reviewed the attached questionnaire and made several suggestions, which were incorporated. (See Attachment 1). Although I was not responsible for the sample or mailing, the methods used seem scientifically valid.

I consulted and considered the following document, after approving this study design: Lilly's experts proposed testimony of market share, (Attachment 5).

I met personally with you and Peter Steere to review their familiarity and insights into the dynamics and chronology of this market and to discuss some of the challenging issues we were facing:

- a. How could we insure that the memories of the target group were reliable?
- b. What number of returns would constitute as sufficient sampling?
- c. What were the variables in the twelve-year period under study and how did this impact on the years selected?
- d. What were the prescribing habits of various physicians prescribing this drug, i.e. how was the drug prescribed?
- e. What were the indications for these prescriptions?

My responsibility with respect to the survey is outlined in my letter of agreement of April 13, 2004 (Attachment 6) in broad terms, I agreed to analyze, aggregate and summarize data from the pharmacist's survey regarding dispensing of Stilbestrol/Diethylstilbestrol (DES) in the 1960's.

### Overview

A one page 11-item survey was sent to 370 currently licensed pharmacists who were originally licensed 1/1/63—6/30/67. (See Attachment 1) I received 159 responses of which 6 were duplicates. My analysis is based on the 153 unduplicated responses, a 41.4% return rate). Of these 153 responses 79 practiced in Massachusetts at some time from 1963 to 1967 (question 5) in a pharmacy which stocked DES in the pregnancy dosages (question 8). Of these 79 respondents 71 (89.9%) volunteered Lilly as the most likely brand to be dispensed (question 9), 2 (2.5%) volunteered Lilly along with other brands, 5 (6.3%) could not remember, and 1 (1.2%) volunteered a different brand (Upjohn).

Thirteen cases initially eliminated from consideration were reinstated in the follow up process.

To test statistical significance my null hypothesis is that pharmacies are as likely to dispense non Lilly DES as Lilly DES. Using the nomenclature of Ted Colton *Statistics in Medicine* (Little Brown, NY, 1974, p159) assume 0.05 is a small enough chance to reject the null hypothesis. The Lilly response  $p=0.899$  and  $\pi=0.5$ . The critical ratio  $z_c=6.99$ . Using a two-tailed normal distribution  $P<0.003$ . The null hypothesis is rejected. In other words, the observed percentage of Lilly preference is very unlikely to come about by chance.

### Analysis Process

The survey instrument is provided as Attachment 1. The instrument contains 9 open-ended questions and 2 close-ended questions. Data from each form were transcribed to a computer file using a specially designed program. After removal of duplicates the open ended responses were reorganized on a question-by-question basis using a second specially designed program. The result is provided as Attachment 2. The close-ended questions were read into SPSS statistical software. Frequency counts and a cross tabulation are provided as Attachment 3.

### Questions 1-4

This personal address information is useful should follow up be required to clarify a response. These responses are bundled in the Section One of Attachment 2.

### Question 5

The response identifies respondents who were retail pharmacists in Massachusetts either in 1965 or in the period 1963 to 1967, depending on which questionnaire the respondent

received. Of 153 unduplicated responses, 100 answered this question "yes", 66.2% of those who answered the question. See attachment 3.

This question was originally asked "During the period 1965 ...". Later questionnaires modified the date to "1963-1967". The follow up process contacted the respondents who had received the first questionnaire and who did not answer "yes". Thirteen provided new responses that are included in the survey rather than their original responses.

### ***Questions 6 and 7***

The response to this question identifies the name and location of the pharmacy in which the respondent practiced if the respondent answered question 5 "yes". The responses are in Section Two of Attachment 2. They represent locations widely scattered across the commonwealth.

### ***Question 8***

The response identifies respondents whose pharmacies stocked and dispensed DES in the pregnancy dosage during the 60's. Of 153 unduplicated responses, 89 (58.2%) answered this question "yes", 78.8% of those who answered the question. See attachment 3.

### ***Question 9***

This key question asks the respondent what brand of DES was most likely dispensed if the prescription did not name a brand. The question is open ended, providing no prompts. Only the 79 respondents who answered "yes" to both questions 5 and 8 qualified for analysis. Of the 79, 71 volunteered "Lilly" as reported above. To obtain this result Section Three of Attachment 2 containing the responses to question 9 is used. A listing of responses to questions 5 and 8 is used to identify the qualified group and the number of "Lilly" and other kinds of response are tabulated by inspection.

### ***Question 10***

This question provides space for respondent comment. Most respondents did not comment; see Section Four of Attachment 2. A few comments relevant to the survey:

- I do remember seeing DES by Brewer & Co. and also Parke-Davis because I worked in prescription department from 1959 until became registered in 1965 but by that time I believe the DES we used was Lilly.
- I only recall the Lilly brand at that time.
- Lilly was the #1 supplier of generics then.
- Squibb was also used. I recall 5g. tabs and am pretty sure we had 25g.
- Extremely frequently prescribed by many physicians to many women or all ages.
- I believe that we only stocked Lilly's brand but I could be mistaken. That was a long time ago!

### ***Question 11***

This question solicits the name of the wholesaler. Responses are provided in Section Five of Attachment 2. Among those frequently cited, in order of frequency of citation:

Gilman, James W. Daly, McKesson, Mass Wholesale, United Consumers, New England Wholesale.

### *Conclusions*

My conclusions are as follows:

1. The survey is trustworthy and based on a well-grounded sampling, considering the past time of the event we are considering.
2. Hearsay and memory risks were satisfactorily minimized.
3. The numbers of possible responders was properly surveyed to obtain a representative sample.
4. The questionnaire contained clear, precise and non-leading questions, which were answered appropriately consistent with the sources of information.
5. The responders had no knowledge of the litigation nor could they have been influenced or sympathetic to any individual or company.
6. The mailings, return receipts and collating protected the security and impartiality of the survey.
7. My statistical analysis was in accordance with accepted and standard epidemiological procedures.
8. The study and its results meet or surpass the assignment I undertook as contained in a letter to you from an attorney who I understand represents DES daughters seeking compensation from the manufacturer. (See Attachment 4). However, neither this attorney, nor anyone else engaged in such litigation nor any of the claimants have played any role in the design or conduct of this survey or my conclusions.
9. This study is adequately free from any bias that could invalidate the results.
10. The Lilly experts' opinions (Attachment 5) do not focus on the State of Massachusetts or the time period, and are therefore invalid in answering the pertinent questions.

Based on the foregoing analysis I conclude to a reasonable degree of statistical certainty and within reasonable principles of sample surveying that the Lilly brand would have been dispensed in 90 out of 100 instances in response to prescriptions for DES that did not designate a brand within the Commonwealth of Massachusetts between the years 1963 to 1967. The error in this rate is  $\pm 6$ . This conclusion can be extended to other years in so much as dispensing habits did not change.

Sincerely,



Hannelore Vanderschmidt, PhD, Ed.M  
Co-Director, Center for Educational Development in Health  
Adjunct Associate Professor of Public Health, Boston University

# **APPENDIX 23**

UNITED STATES DISTRICT COURT  
CENTRAL DISTRICT OF CALIFORNIA

CIVIL MINUTES - GENERAL

☒ Priority  
☒ Send  
☐ Clsd  
☐ Enter  
☐ JS-5/JS-6  
☐ JS-2/JS-3

Case No. SACV 03-0962 CJC (CTx)

Date: July 22, 2003

Title: LYNN MANDELL KOGEN V. ELI LILLY & COMPANY

DOCKET ENTRY: ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT FILED JUNE 2, 2003

PRESENT:

HONORABLE CORMAC J. CARNEY, UNITED STATES DISTRICT JUDGE

Cynthia Salver  
Deputy Clerk

N/A  
Court Reporter

ATTORNEYS PRESENT FOR PLAINTIFF:

ATTORNEYS PRESENT FOR DEFENDANT:

None Present

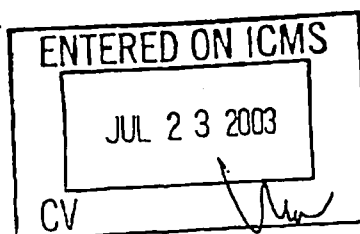
None Present

PROCEEDINGS: DEFENDANT ELI LILLY'S MOTION FOR SUMMARY JUDGMENT  
(6/2/03)

Defendant's motion for summary judgement is DENIED. There are triable issues of fact concerning whether Mrs. Kogen's cervical changes were caused by DES and whether the DES taken by Mrs. Mandell was manufactured by Lilly. Plaintiff has put forth credible expert medical testimony showing that Mrs. Kogen has a T-shaped uterus as a result of DES exposure. Plaintiff also has put forth credible evidence showing that Mrs. Kogen's mother took a white-cross medication during her pregnancy specifically for spotting, that the white-cross medication was DES, and that Lilly produced the white-cross DES drug during the relevant time period.

cc: All Parties of Record

MINUTES FORM 11  
CIVIL-GEN



Initials of Deputy Clerk

*[Handwritten initials]*  
*[Handwritten initials in a circle]*

# **APPENDIX 24**

UNITED STATES DISTRICT COURT  
WESTERN DISTRICT OF WASHINGTON  
AT SEATTLE

KELLY ANN WOOLFOLK,

Plaintiff,

v.

ELI LILLY AND COMPANY, et al.,

Defendants.

CASE NO. C03-3577RSM

ORDER ON MOTION FOR SUMMARY  
JUDGMENT

This matter is before the Court on defendant's Motion for Summary Judgment (Dkt. # 37). The Court heard oral argument on the matter on March 4, 2005, and has fully considered the memoranda and exhibits filed by the parties. For the reasons set forth below, defendant's motion is DENIED.

DISCUSSION

Plaintiff Kelly Woolfolk suffers from long-standing infertility, and has been diagnosed with a "T-shaped" uterus and cervical abnormalities. She alleges that her condition was caused by her mother's ingestion of the hormone diethylstilbesterol ("DES") during pregnancy, and she seeks compensation for her injury from the manufacturers of this product. The complaint was originally filed in Washington, D.C. Superior Court, removed to D.C. District Court, and then transferred to this district. Defendant asserts that under Washington D.C. choice of law provisions, the substantive law of Washington State applies to this action, and plaintiff does not dispute this. Plaintiff alleges four separate theories of liability: (1) negligence in failure to test and failure to warn; (2) strict liability; (3) breach of express and implied warranty; and (4) misrepresentation. She also claims punitive damages. Two named defendants

ORDER ON MOTION FOR SUMMARY  
JUDGMENT- 1

1 have arrived at settlement with the plaintiff and have been dismissed from this action, leaving only Eli  
2 Lilly and Company.

3 Defendant has moved for summary judgment on the bases that (1) the breach of warranty claim is  
4 time-barred; (2) the strict liability and punitive damages claims fail as a matter of law; and (3) plaintiff has  
5 no admissible evidence to prove that her mother actually took DES during her pregnancy, or, if she did,  
6 that it was manufactured by Eli Lilly. Plaintiff waived her claims as to strict liability and punitive  
7 damages at the hearing, but asserted the discovery rule as a defense to the statute of limitations bar. The  
8 statute of limitations issue will be addressed below; the Court turns first to defendant's argument that  
9 plaintiff has no admissible evidence to support her claim.

10 Plaintiff was born in 1970. Her mother, Deann Mills, recalls that she was prescribed "a hormone"  
11 which was supposed to prevent miscarriage. It is undisputed that DES was routinely prescribed at that  
12 time for that purpose, but it was not the only such hormone used. The doctor who treated Deann Mills  
13 is now dead, and the medical records of her pregnancy are not available. At her deposition, Ms. Mills  
14 stated that she did not recall the name of the hormone, and she had never heard of DES or  
15 diethylstilbesterol before March of 2000. She did not remember the color of the pills she took, only that  
16 they were round in shape. Later, in response to the summary judgment motion, Ms. Mills presented an  
17 affidavit stating that "[a]lthough I do not recall the exact name or color of the hormone, I do recall that it  
18 was a long word beginning with a "D" and that it was not a yellow pill." However, a party cannot  
19 survive summary judgment by contradicting his or her own sworn deposition with a later declaration.  
20 Harris v. City of Seattle, 315 F. Supp. 2d at 1105, *quoting* Disc Golf Association v. Champion Discs,  
21 Inc., 158 F. 3d 1002, 1008 (9<sup>th</sup> Cir. 1998). While Ms. Mills' memory may be explored on cross-  
22 examination at trial, her affidavit will not be considered on summary judgment.

23 Plaintiff has also presented an affidavit by her father, Robert Grinnell, now divorced from Ms.  
24 Mills. Mr. Grinnell states that his former wife took DES during her pregnancy, and that it was a white  
25 pill with cross-shaped scoring on it. As to the identification of DES these statements are, as defendant  
26 argues, hearsay. Plaintiff subsequently provided an amended affidavit by Mr. Grinnell, stating that he  
27 filled the prescription because his wife was confined to bed, and he personally observed the label on the  
28

1 bottle and the size, shape, and color of the pills. Defendant objected to this affidavit on the grounds that  
2 Mr. Grinnell has never been disclosed as a witness. However, plaintiff adequately explained that failing,  
3 in that Mr. Grinnell could not be located until recently. He has now been disclosed and defendant has an  
4 opportunity to depose him before trial. For the purposes of this summary judgment motion, the amended  
5 affidavit will be considered by the Court.

6 Plaintiff has also presented her medical records and expert testimony on causation. While  
7 plaintiff's medical records themselves are admissible evidence, any mention of DES exposure is, without  
8 an adequate foundation to establish the basis for the diagnosis, simply hearsay. However, the Court finds  
9 that the deposition testimony of Gilbert Mottla, M.D., stating "to a reasonable degree of medical  
10 probability" that plaintiff's anatomical abnormalities are consistent with DES exposure constitutes  
11 admissible evidence sufficient to defeat summary judgment. Dr. Mottla submitted a declaration  
12 establishing his credentials as an expert and the fact that he has authored a published, peer-reviewed  
13 article on DES exposure. His testimony regarding the connection between DES exposure and a "T-  
14 shaped" uterus is supported by the medical textbook excerpts supplied by plaintiff. Although Dr. Mottla  
15 conceded that no single abnormality is exclusive to DES exposure, he consistently testified that the  
16 particular combination of symptoms presented by plaintiff is diagnostic of DES exposure. The Court  
17 thus concludes that plaintiff has presented sufficient evidence to create triable issues of fact regarding her  
18 exposure to DES manufactured by defendant, and whether her particular injuries were caused by that  
19 exposure.

20 The application of the statute of limitations was only briefly explored at the hearing: defendant  
21 asserted that under the transferor court's choice of law provision, it is the District of Columbia statute of  
22 limitations which applies. No argument was heard on how to apply this statute of limitations to the facts  
23 of this case. In a letter to the Court received one week after the hearing, defendant asked for an  
24 opportunity to further brief the matter. The Court deems that unnecessary.

25 The District of Columbia courts apply a "discovery rule" to determine when the statute of  
26 limitations begins to run. A plaintiff must file suit within three years of the date when she knew, or by the  
27 exercise of reasonable diligence should have known, (1) of the injury, (2) of the cause in fact of the  
28

1 injury, and (3) of some evidence of wrongdoing by the defendant. Albers v. Eli Lilly and Company, 257  
2 F. Supp. 2d 1147, 1149 (N.D.Ill. 2003); citing Diamond v. Davis, 680 A.2d 364 (D.C.App. 1996). In  
3 Albers, the district court applied the discovery rule to bar a plaintiff's suit because she did not file until  
4 ten years after she was diagnosed with a T-shaped uterus from DES exposure. The plaintiff asserted that  
5 she did not have "some evidence of wrongdoing" until 1999 or 2000 when she saw a newspaper ad  
6 regarding DES suits. Albers v. Eli Lilly and Company, 354 F. 3d 644, 645 (7<sup>th</sup> Cir. 2004). The court  
7 ruled that reasonable investigation would have turned up "some evidence" of wrongdoing earlier. Id.

8 Defendant, citing Albers, attached to the letter a notation in plaintiff's medical record from 1999,  
9 indicating a history of DES exposure. Defendant argues that this was sufficient notice to plaintiff of her  
10 injury to start the statute running. However, that notation is, as defendant argues earlier, hearsay.  
11 Further, with respect to the three-step discovery rule analysis, it does not adequately establish either  
12 injury or the cause of such injury. Indeed, the history recitation in the record provided by defendant  
13 states that "[s]he has been told in the past that she does not have DES characteristics but has always been  
14 concerned about that." (Emphasis added). The exam on that day in 1999 was inconclusive and plaintiff  
15 was referred for further evaluation of her infertility. According to the medical records supplied by  
16 plaintiff, she was diligently investigating the source of her infertility during this time. It was not until a  
17 hysterosalpingogram was performed in March 2000, that the uterine shape abnormality was discovered.  
18 The July 16, 2001 record from the Virginia Mason Medical Center refers to a note in the file written  
19 March 17, 2000, describing a "DES pattern" in the shape of the uterine cavity. The doctor's notes from  
20 July 16, 2001 confirm the diagnosis of DES exposure, and the relation to infertility.

21 When these facts are viewed in the light most favorable to plaintiff, as appropriate on summary  
22 judgment, they lead to the conclusion that the statute of limitations began to run, at the earliest, either in  
23 March of 2000, or July of 2001, when plaintiff discovered the exact nature of her uterine abnormality, the  
24 cause of her infertility, and the connection to DES exposure.<sup>1</sup> Using either date, this suit filed February  
25

---

26 <sup>1</sup>Under District of Columbia law regarding the statute of limitations, "when accrual actually  
27 occurred in a particular case is a question of fact for the factfinder." Albers, 257 F. Supp. 1at 1150;  
28 quoting Doe v. Medlantic Health Care Group, Inc., 814 A.2d 939 (D.C.App. 2003).

1 19, 2003 is timely.

2 Plaintiff has presented sufficient evidence to create triable issues of fact regarding her exposure  
3 to DES manufactured by defendant, and whether her particular injuries were caused by that exposure.  
4 She has also presented evidence from which a jury could find that her cause of action did not begin to  
5 accrue until she learned, following specific diagnostic procedures, of the actual malformation of her  
6 uterus, and its relation to DES exposure. Accordingly, defendant's motion for summary judgment is  
7 DENIED.

8  
9 DATED this 15 day of March 2005.

10  
11 /s/ Ricardo S. Martinez  
12 RICARDO S. MARTINEZ  
13 United States District Judge  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25  
26  
27  
28

# **APPENDIX 25**

This message has been scanned for known viruses.

From: DCD\_ECFNotice@dcd.uscourts.gov  
To: DCD\_ECFNotice@dcd.uscourts.gov  
Subject: Activity in Case 1:03-cv-01796-EGS-AK BROOKS v. ELI LILLY AND COMPANY et al "Order on Motion for Summary Judgment"  
Date: Thu, 28 Jul 2005 14:15:33 -0400 (EDT)

\*\*\*NOTE TO PUBLIC ACCESS USERS\*\*\* You may view the filed documents once without charge. To avoid later charges, download a copy of each document during this first viewing.

U.S. District Court

District of Columbia

Notice of Electronic Filing

The following transaction was received from lcegs1, entered on 7/28/2005 at 2:15 PM and filed on 7/28/2005

Case Name: BROOKS v. ELI LILLY AND COMPANY et al

Case Number: 1:03-cv-1796

Filer:

Document Number:

Docket Text:

MINUTE ORDER denying [42] Motion for Summary Judgment, granting [44] Motion for Joinder, granting [46] Motion for Joinder, denying as moot [53] Motion for Hearing. Upon consideration of defendants' motion for summary judgment, the opposition thereto and the reply in support thereof, and for the reasons stated by Judge Martinez in Woolfolk v. Eli Lilly and Co., et al., No. C03-3577 (W.D. WA. March 15, 2005), this Court concludes that Plaintiff has presented sufficient evidence that there are triable issues of fact and thus defendants' motion must be DENIED. Signed by Judge Emmet G. Sullivan on July 28, 2005. (lcegs1)

The following document(s) are associated with this transaction:

1:03-cv-1796 Notice will be electronically mailed to:

Sarah Alyssa Altschuller saltschuller@foleyhoag.com,

John F. Anderson john.anderson@troutmansanders.com

Malcolm S. Brisker msb@gdldlaw.com, bzm@gdldlaw.com

Kathleen M. Bustraan bustraan@lordwhip.com, quigg@lordwhip.com

Janet K. Coleman jcoleman@whitneybogris.com,

James J. Dillon jdillon@foleyhoag.com, bhenninger@foleyhoag.com

Elizabeth Ewert elizabeth.ewert@dbr.com, Stephanie Albert@dbr.com

Roberta Koss koss@hugheshubbard.com, adkins@hugheshubbard.com

Sidney G. Leech sgl@gdldlaw.com, msb@gdldlaw.com

Aaron M. Levine aaronlevinelaw@aol.com

Jeffrey J. Lopez lopezjj@dbr.com,

Lawrence Hedrick Martin lmartin@foleyhoag.com, wvalenti@foleyhoag.com;bhenninger@foleyhoag.com

1:03-cv-1796 Notice will be delivered by other means to:

Aaron L. Handelman  
ECCLESTON & WOLF  
2001 S Street, NW  
Suite 310  
Washington, DC 20009

Melanie H. Muhlstock  
GOODWIN PROCTER, LLP  
5599 Lexington Avenue

# **APPENDIX 26**

APR 16 2004 4:19 PM

202 8333046

NQ 9/0

### Statement of James P. DellaVolpe

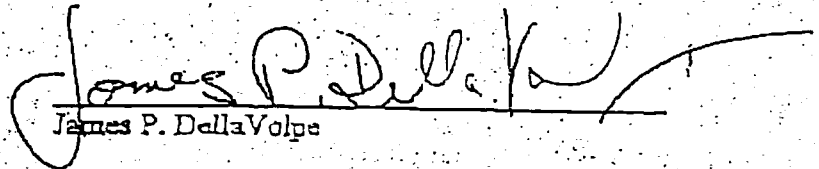
1. I reside at 29 Benedict Road, Buzzards Bay, Massachusetts 02532.
2. I was employed in the 1960's by the McKesson and Robins Company, a full service wholesale drug distributor, located in Canton, Massachusetts. This was a primary distribution center for pharmaceuticals in the Boston area.
3. My employment, as a pharmacy distribution specialist in the warehouse, consisted of selecting prescription medication off the shelves in order to fill orders from retail pharmacies in the Boston area.
4. In the exercise of this responsibility I had the opportunity to observe hundreds of drugs, their packaging, doses, brands and positions on the shelves.
5. All of the drugs in the facility were on shelves in alphabetical order by name of drug, except for the Eli Lilly Company.
6. McKesson and Robins was a "Lilly wholesaler". This meant that if a drug was ordered without a brand specification, that is, it was ordered "unspecified," a Lilly brand would have been supplied in furtherance of the agreement, which McKesson/Robins had with the Lilly Company. The ordinary routine and customary way of filling orders which were not specified by brand name would have been to ship a Lilly product, if they made it. Lilly made DES.
7. When a retail pharmacist in the Boston area would have ordered "DES", "Diethylstilbestrol" or "Stilbestrol", I would have immediately gone to the Lilly section and filled the order with the Lilly brand of DES.
8. I have, in my minds eye, the Lilly brand of DES as stocked in McKesson and Robins in the 60's, but do not recall that any other brand was stocked or ordinarily distributed.

APR. 16. 2004 4:19PM 202 8338046

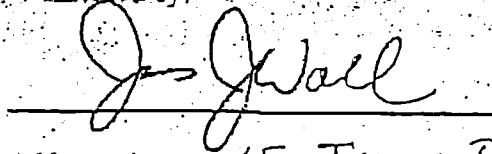
NO. 970 P. 3

I state under penalty of perjury that the above statement is true and correct. Executed this

22 day of 04, 2004.

  
James P. DellaVolpe

Witnessed by:

  
\_\_\_\_\_

Addressed:

15 Joanna Dn  
Foxborough MA